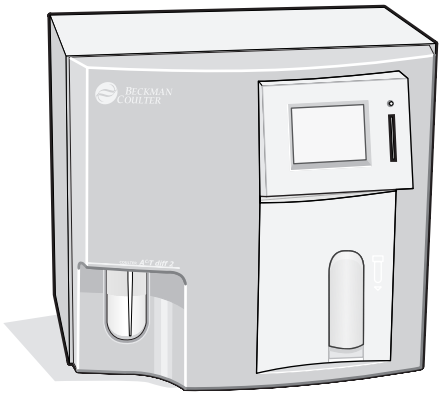
COULTER® A^{C}•T diff 2™ Analyzer

Operator's Guide



PN 4237495A (February 1999)

COULTER CORPORATION
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LEGAL NOTICES

READ ALL PRODUCT MANUALS AND CONSULT WITH BECKMAN COULTER-TRAINED PERSONNEL BEFORE ATTEMPTING TO OPERATE INSTRUMENT.

HAZARDS AND OPERATIONAL PRECAUTIONS AND LIMITATIONS

WARNINGS, CAUTIONS, and IMPORTANTS alert you as follows:

WARNING - Might cause injury.
CAUTION - Might cause damage to the instrument.
IMPORTANT - Might cause misleading results.

CAUTION System integrity might be compromised and operational failures might occur if:

- This equipment is used in a manner other than specified. Operate the instrument as instructed in the Product Manuals.
- You introduce software that is not authorized by Beckman Coulter into your computer. Only operate your system's computer with software authorized by Beckman Coulter.
- You install software that is not an original copyrighted version. Only use software that is an original copyrighted version to prevent virus contamination.

Beckman Coulter, Inc. urges its customers to comply with all national health and safety standards such as the use of barrier protection. This may include, but it is not limited to, protective eyewear, gloves, and suitable laboratory attire when operating or maintaining this or any other automated laboratory analyzer.

WARNING Risk of operator injury if all covers are not secured in place prior to instrument operation or you attempt to replace a part without carefully reading the replacement instructions. Do not attempt to replace any component until you carefully read the instructions for replacing the component.

IMPORTANT If you purchased this product from anyone other than Beckman Coulter or an authorized Beckman Coulter distributor, and, if it is not presently under a Beckman Coulter service maintenance agreement, Beckman Coulter cannot guarantee that the product is fitted with the most current mandatory engineering revisions or that you will receive the most current information bulletins concerning the product. If you purchased this product from a third party and would like further information concerning this topic, call your Beckman Coulter Representative.

REVISION STATUS

Initial Issue, 2/99
Software Version 1.0

This document applies to the latest software listed and higher versions. When a subsequent software version changes the information in this document, a new issue will be released.

REVISION STATUS

CONTENTS

TABLES

This introductory section contains the following topics:

- How to use your COULTER® A^{C}•T diff 2™ Analyzer Manuals
- About this Manual
- Conventions
- Graphics
- Symbols
- Installation Procedures
- Touch Screen Icons
- Icon Tree Overview
- Icon Tree Detail

HOW TO USE YOUR COULTER® A^{C}•T diff 2™ ANALYZER MANUALS

Use this **Operator's Guide** for:

- Getting started
- Running your instrument day to day
- Reviewing unusual results, including how to read a result report and what flags mean
- Performing special procedures such as cleaning, replacing, or adjusting a component of the instrument
- Troubleshooting problems with your instrument.

Use the **Reference** manual for in-depth information about:

- What the instrument does
- What special requirements the instrument has (for example, space, accessibility, power)
- What methods it uses
- What the instrument specifications are
- How to interface your A^{C}•T diff 2 analyzer to your laboratory's host computer
- How to safely use the instrument.

Use the **Operating Summary** for:

- Running your instrument using a quick reference set of procedures
- Verifying screen icon definitions

Use the **Installation and Training Guide** for:

- Initially setting up the instrument and printer
- Powering up the instrument
- Customizing the software
- Running controls and samples

ABOUT THIS MANUAL

This information in this manual is organized as follows:

- Chapter 1, Routine Procedures
  Contains the startup and shutdown procedures.
- Chapter 2, Cell Controls
  Contains information on 4C® PLUS cell control.
- Chapter 3, Running Samples
  Contains information on how to run whole blood and prediluted blood samples.
- Chapter 4, Reviewing Results
  Contains information on how to review current and stored sample results.
- Chapter 5, Calibration
  Contains the procedures for reproducibility, carryover, and auto-calibration. Also includes precalibration checks.
- Chapter 6, Service and Maintenance
  Contains information on the special procedures and troubleshooting procedures for the instrument. Covers topics such as cleaning, calibration, replacement and adjustment procedures, as well as defining flags and codes.
- Appendix A, Manual Calibration
  Contains the procedures for manual calibration when S-CAL® calibrator is not available.
- Appendix B, Tubes and Adapters
  Contains a list of approved tubes and tube adapters for use with the instrument.
- This manual also includes a Glossary, Abbreviations list, recommended References, and an Index.

CONVENTIONS

This manual uses the following conventions:

Bold font indicates A^C•T diff 2 analyzer manual titles.

Bold indicates a screen icon.

Italics font indicates screen text displayed by the instrument.

Instrument refers to the A^C•T diff 2 analyzer.

A Note contains information that is important to remember or helpful in performing a procedure.

GRAPHICS

All graphics, including screens and printouts, are for illustration purposes only and must not be used for any other purpose.

SYMBOLS

Safety Symbols

Safety symbols alert you to potentially dangerous conditions. These symbols, together with text, apply to specific procedures and appear as needed throughout this manual.

Symbol	Warning Condition	Action
	**Biohazard**.Consider all materials (specimens, reagents, controls, and calibrators, and so forth) as being potentially infectious.	Wear standard laboratory attire and follow safe laboratory procedures when handling any material in the laboratory.
	**Probe hazard.** The probe is sharp and may contain biohazardous materials, including controls and calibrators.	Avoid any unnecessary contact with the probe and probe area.
	**Electrical shock hazard**. Possibility of electrical shock when instrument is plugged in to the power source.	Before continuing, unplug the A^{C}•T diff 2 analyzer from the electrical outlet.

Procedure Symbols

Procedure symbols give direction.

Symbol	Definition	Action
	**Go to step number**.	Go to the step number that appears after the icon.
	**Special Procedures and Troubleshooting**	See Special Procedures and Troubleshooting in this manual for additional information.

INSTALLATION PROCEDURES

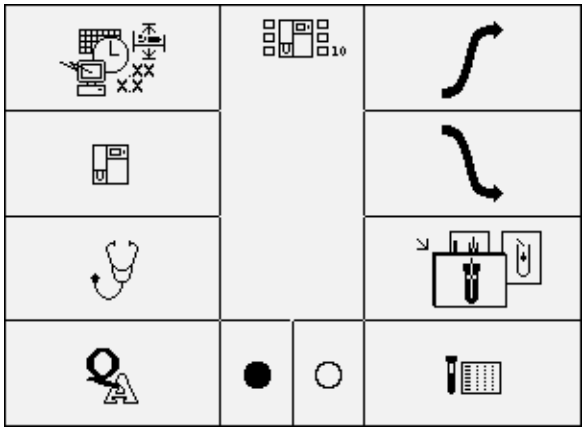
See the Installation and Training Guide for installation procedures.

TOUCH SCREEN ICONS

Screen Numbers

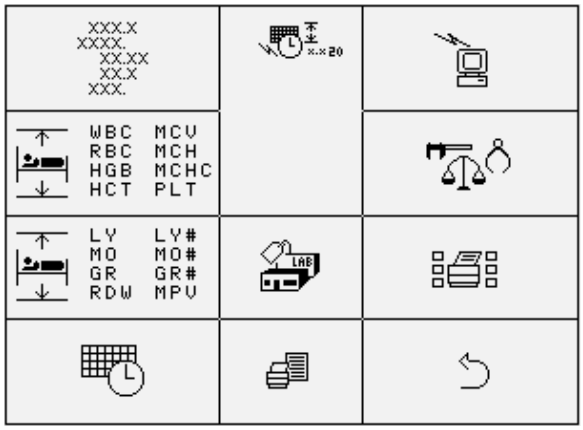
A number appears next to the title icon on a screen. The number is unique to that screen and is significant only as a screen identifier; the number does not print on any reports.

Main Screen Icons



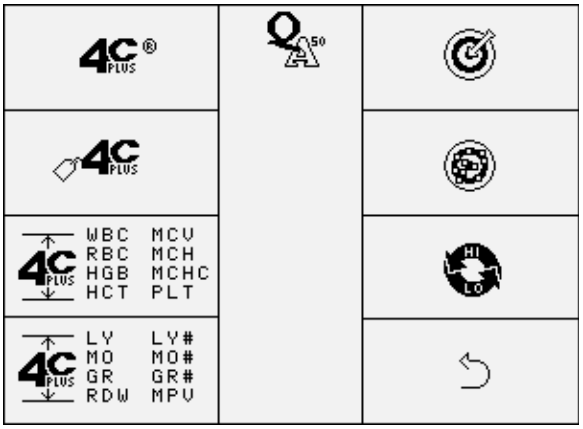
Setup	Startup
Diluter Functions	Shutdown
Diagnostics	Analyzing Mode
Open Vial Whole Blood Mode	Closed Vial Whole Blood Mode
Predilute Mode	Quality Assurance
Darken Screen	Lighten Screen
Sample Results Screen	

Setup Screen Icons



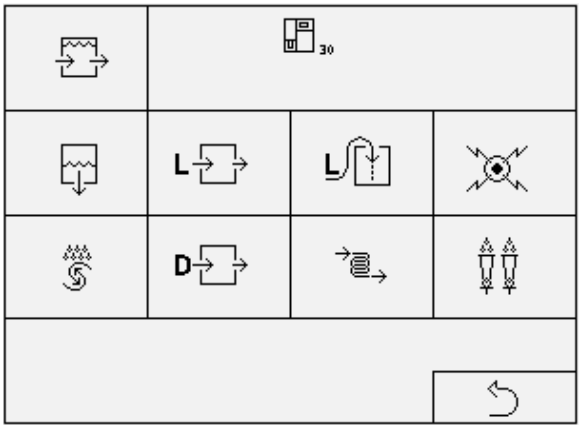
Units	Transmission
Patient Limits	Calibration Factors
Date/Time	Printers/Profiles
Laboratory ID	Exit
Print Setup Report	

QA Screen Icons



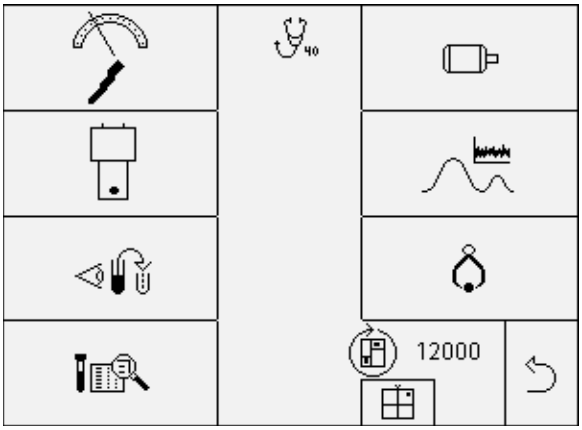
4C PLUS Cell Control Run	Calibration
4C PLUS Management	Reproducibility
4C PLUS Limits	Carryover
	Exit

Diluter Functions Screen Icons



Wet Prime	Dispense Lytic Reagent
Drain Baths	Prime Sweepflow
Rinse + Mix	Zap Apertures
Dry Prime Lytic Reagent	Clean Baths
Dry Prime Diluent	Exit

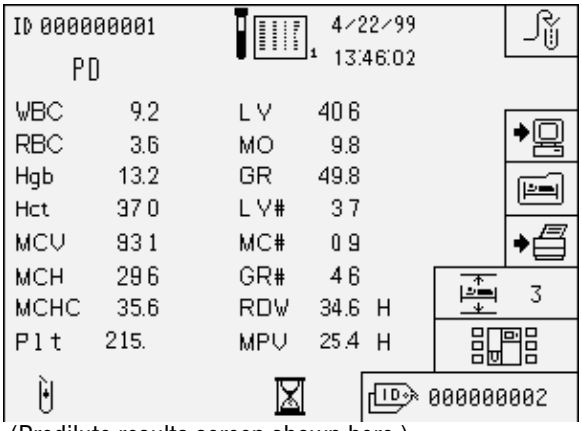
Diagnostic Functions Screen Icons



Voltages/Sensors	Motors†
Solenoids	Pulse Test
Verify Predilute	Latex Calibration
Sample Details	Prepare to Ship
Cycle Counter	Exit

†Do not use this function without proper instruction from your Beckman Coulter Representative.

Sample Results Screen Icons

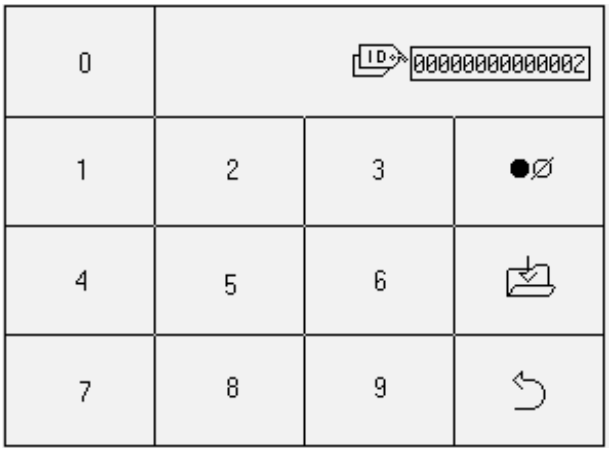


(Predilute results screen shown here.)

Dispense Diluent	Go to Main Menu
Resend to Host	Enter Patient ID
Retrieve Stored Data	In Progress
Print Sample Results	Patient Limits

†Do not use this function without proper instruction from your Beckman Coulter Representative.

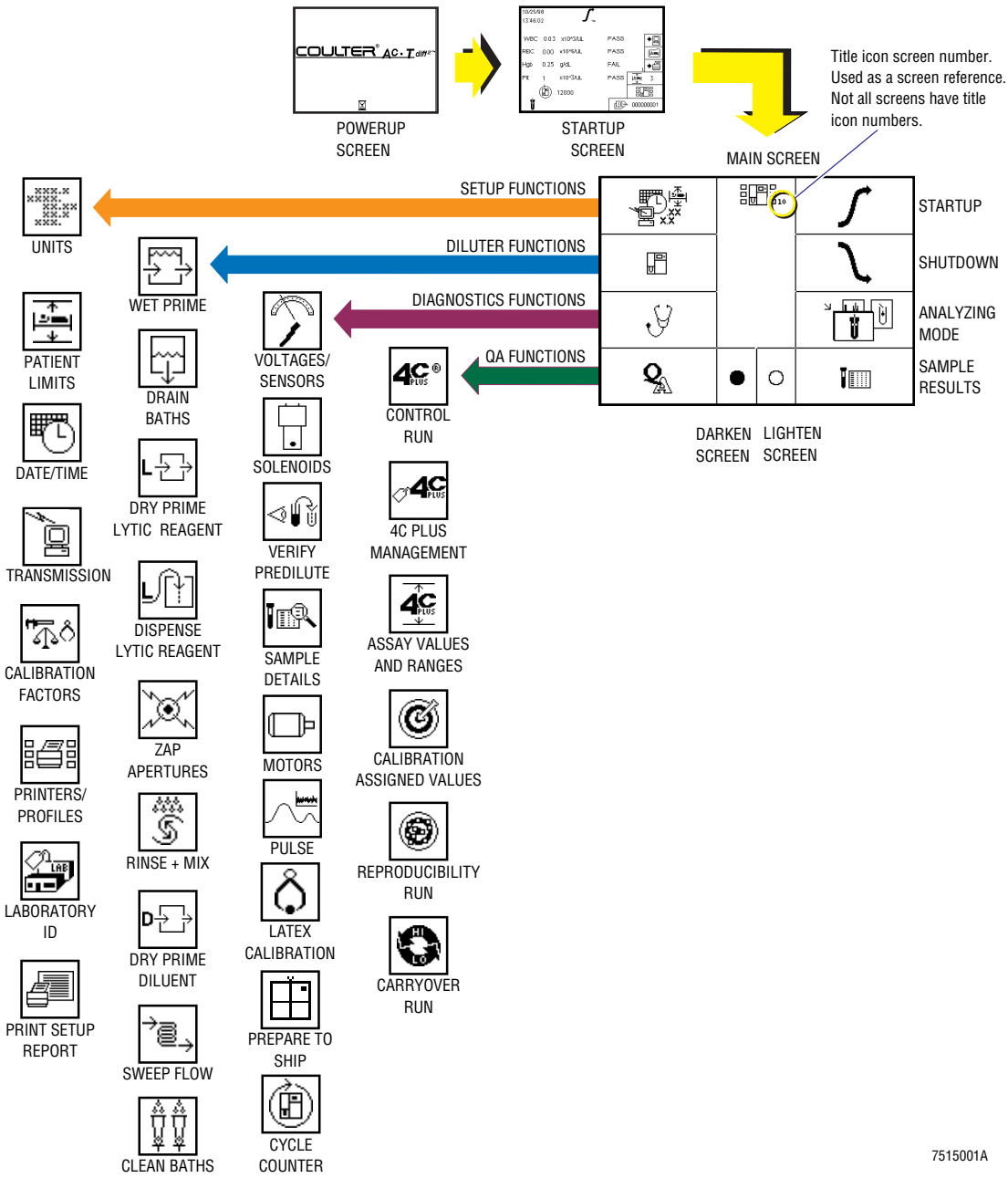
Sample ID Screen Icons



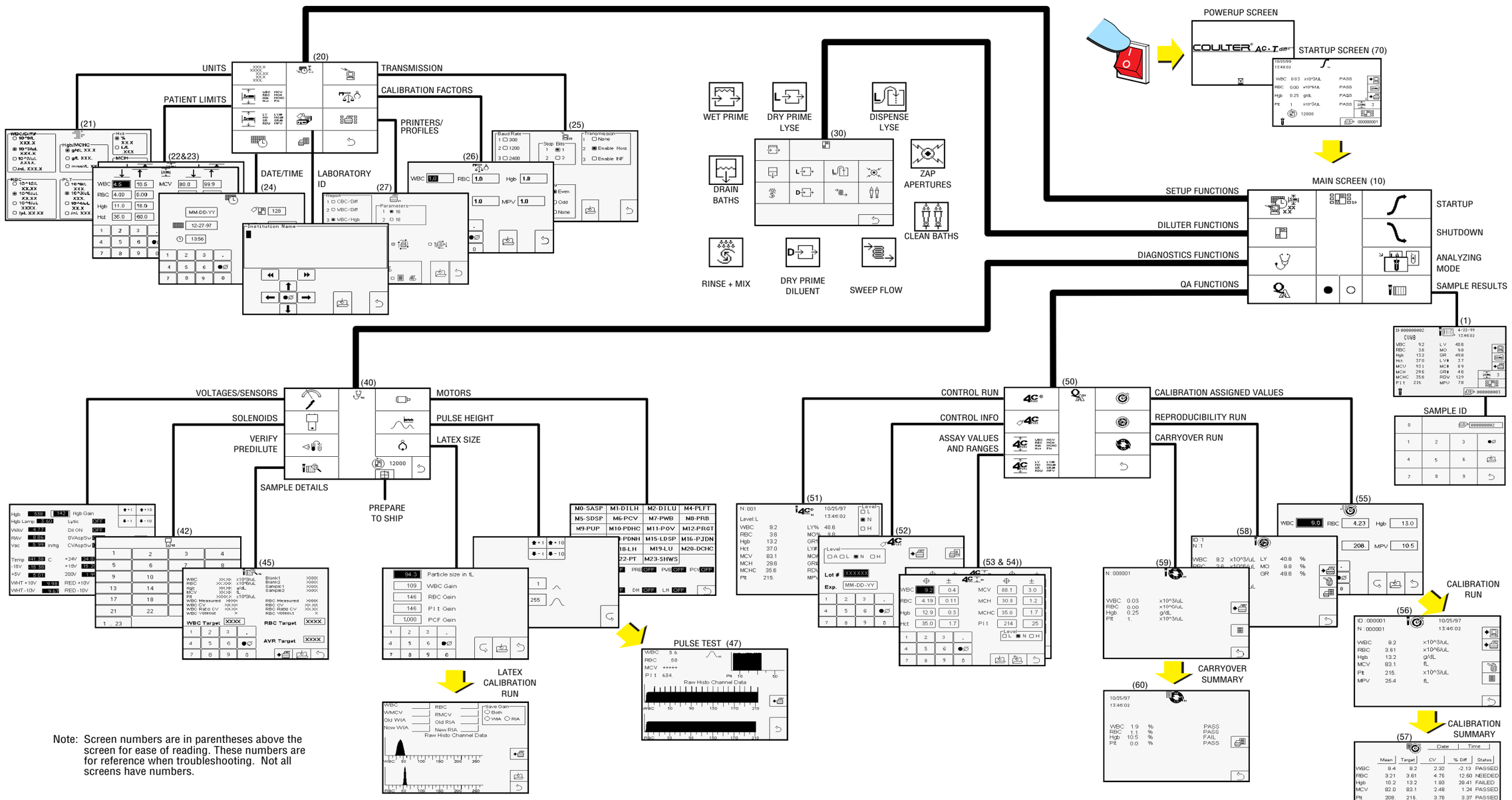
Next Sample ID	Save and Exit
Delete	Exit

ICON TREE OVERVIEW

Here is an overview of the icon tree. For additional information, see Touch Screen Icons and Icon Tree Detail.



ICON TREE DETAIL



Note: Screen numbers are in parentheses above the screen for ease of reading. These numbers are for reference when troubleshooting. Not all screens have numbers.

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1.1 STARTUP

When you turn on the instrument, it automatically performs the startup procedure. If you want to have the instrument do the startup procedure again when the instrument is on, follow this procedure. Do this procedure daily.

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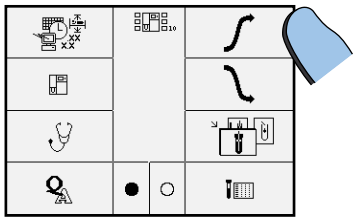
1 At the Main screen, touch the **Startup** icon.



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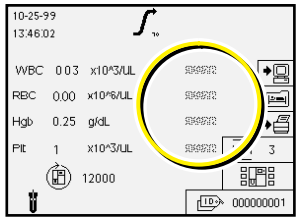
2 The instrument performs the startup routine and reports a *PASS* or *FAIL* for the WBC, RBC, Hgb, and Plt parameters.



1.2 SHUTDOWN

Before you turn the instrument off, do this shutdown procedure. Do this procedure daily. If you consistently run less than 5 samples per day, you can do this procedure every other day.

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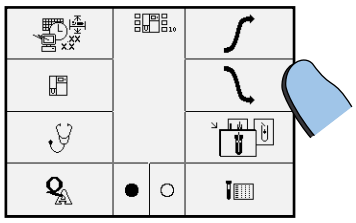
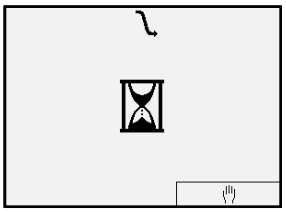
1 At the Main screen, touch the **Shutdown** icon.



2 When this screen appears, you can turn off the instrument.



2.1 ENTERING 4C PLUS CELL CONTROL INFORMATION

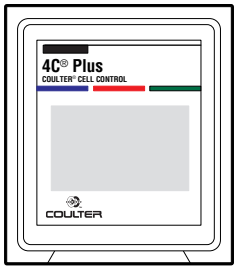
Before running controls, the values from the TABLE OF EXPECTED RESULTS in the assay sheet must be entered and saved into the instrument for each lot of controls.

When operating this instrument outside the optimal temperature range (20° - 25°C), control results may exceed the expected limits. One of the suggested corrective actions is to establish your own mean values that are appropriate for your laboratory's environment. These values should be entered and saved in the instrument. The mean value you establish should not exceed the expected range limits determined for the control material at optimal temperature. If this occurs, contact your Beckman Coulter Representative.

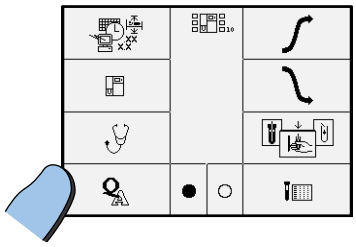
IMPORTANT Risk of existing data in the database not being flagged using new values or ranges. If the Expected Values or Range is edited and saved when the control database is not empty, samples run after the change will be flagged according to the edited values; however, the data already in the database will not be reflagged based on the new values or ranges. The new values will be printed with the control summary data. Be sure to edit/save Expected Values or Ranges only when the control database is empty.

Entering the Lot Number

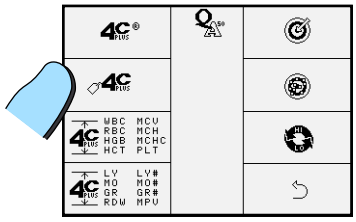
1 Be sure you have the 4C PLUS cell control.



2 At the Main screen, touch the **QA** icon.



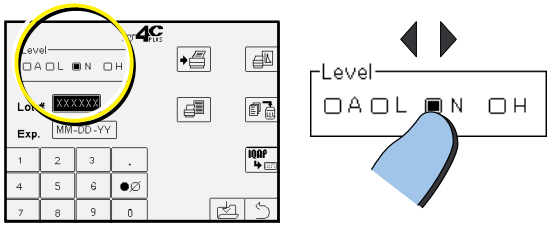
3 At the QA screen, touch the **4C Management** icon.



4 Select the cell control level (**L**, **N**, or **H**) by touching the level indicator.

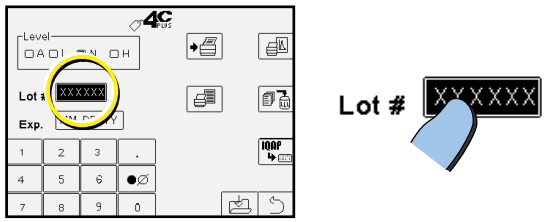
- **A** = all (Not for use when entering the lot number or expiration date.)
- **L** = low
- **N** = normal
- **H** = high

The square darkens next to your selection.

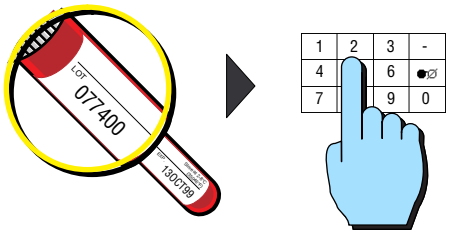


5 Enter the lot number:

a. Touch the Lot# field.

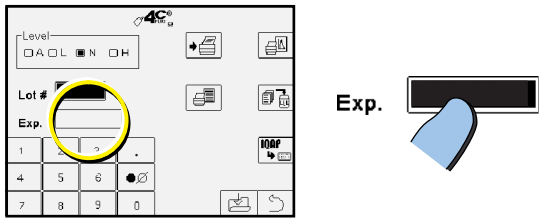


b. Enter the lot number located on the vial (up to 6 digits).



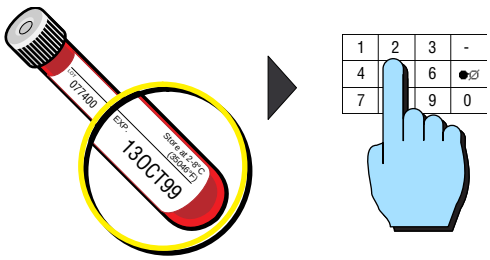
6 Enter the expiration date:

a. Touch the Exp. field.



b. Enter the expiration date (up to 6 digits) in MMDDYY format. Use a dash to separate the month from the day and the day from the year.

For example, to enter October 13, 1998, you would press 10-13-98 at the keypad.



7 Print the information you entered by touching the **Print** icon.

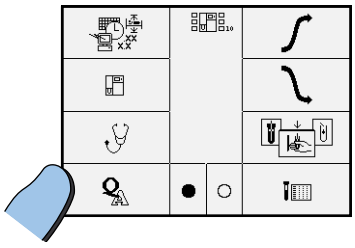
8 Save the information by touching the **Save and Exit** icon.

9 Do the Entering Values procedure.

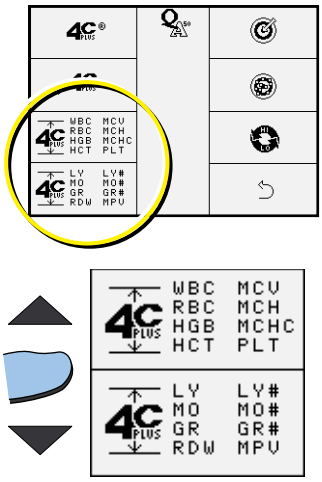
Entering Values

IMPORTANT Risk of misleading results if improper values are entered. If you are not using 4C PLUS cell control, DO NOT do this procedure.

1 At the Main screen, touch the **QA** icon.



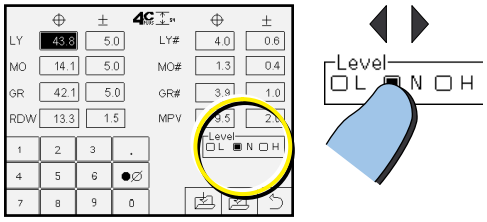
2 At the QA screen, touch one of the **4C Parameter** icons.



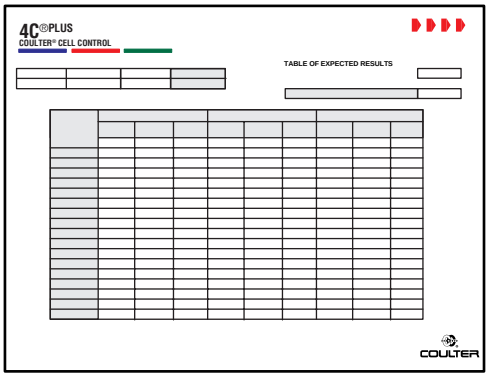
3 Select the control level:

- **L** = low
- **N** = normal, or
- **H** = high.

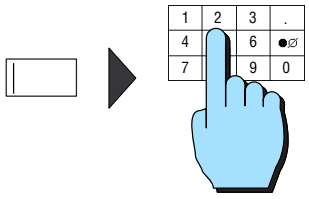
The square darkens next to your selection.



4 Refer to the TABLE OF EXPECTED RESULTS supplied with your control material.

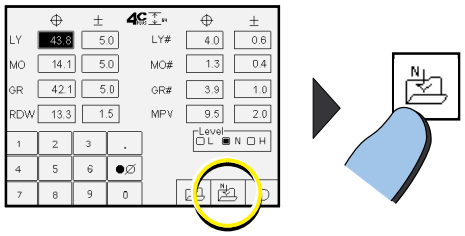


5 On the screen, touch the parameter field where you want to enter the assay values. At the keypad, enter the corresponding expected range from the TABLE OF EXPECTED RESULTS.

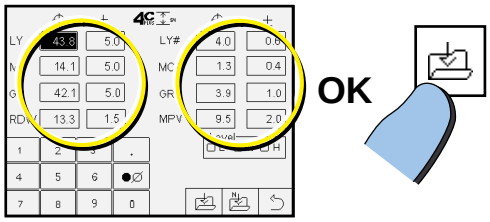


6 To save the data you enter while remaining at the current screen touch the middle icon at the bottom right of the screen. (L, N, or H appears above the **Save** icon to reflect the control level.)

Note: This is recommended if your laboratory experiences electrical fluctuations or brownouts.



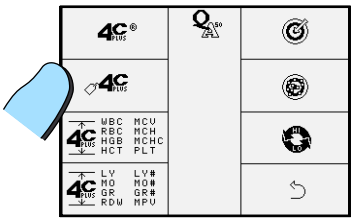
7 When you are ready to save and exit this screen, touch the **Save and Exit** icon.



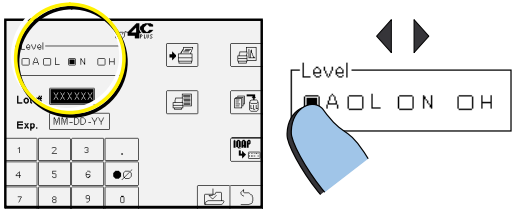
8 Repeat steps 1 through 7 until target values are entered for all levels.

9 To print the values you entered:

a. Return to the QA screen and touch the **4C Management** icon.



b. Select **A** for all.



c. Touch the **Print** icon.

2.2 RUNNING CONTROLS

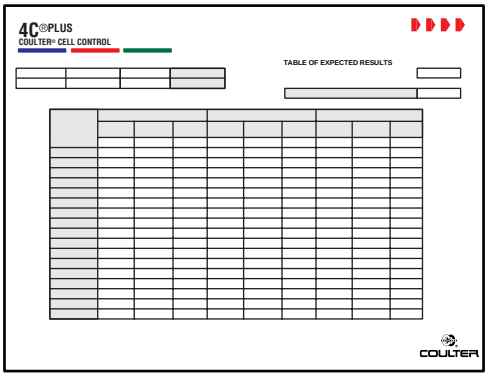
The control for the A^{C}•T diff 2 analyzer is 4C PLUS cell control.

When operating this instrument outside the optimal temperature range (20° - 25°C), control results may exceed the expected limits. One of the suggested corrective actions is to establish your own mean values that are appropriate for your laboratory's environment. These values should be entered and saved in the instrument. The mean value you establish should not exceed the expected range limits determined for the control material at optimal temperature. If this occurs, contact your Beckman Coulter Representative.

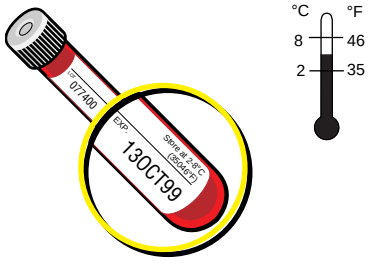
Running COULTER 4C® PLUS Cell Control

1 Be sure the 4C PLUS cell control information and values have been correctly entered from the TABLE OF EXPECTED RESULTS in the assay sheet.

For information on how to enter the values, see Entering Values in this chapter.

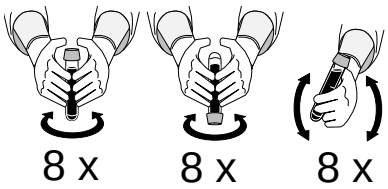


2 Ensure that the 4C PLUS cell control is not past its expiration date and that it is at the correct storage temperature.

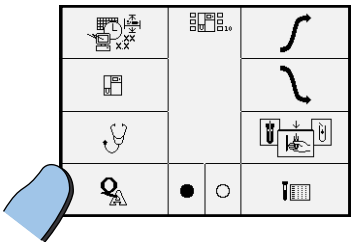


3 After warming at room temperature, mix each control gently according to instructions in the cell control package insert.

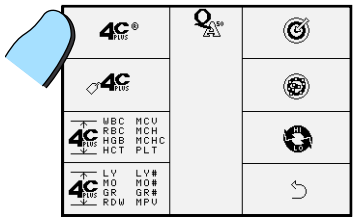
Inspect the vial contents to ensure that all cells are uniformly distributed; if not, repeat this step.



4 At the Main screen, touch the **QA** icon.



5 At the QA screen, touch the **4C PLUS Run** icon.

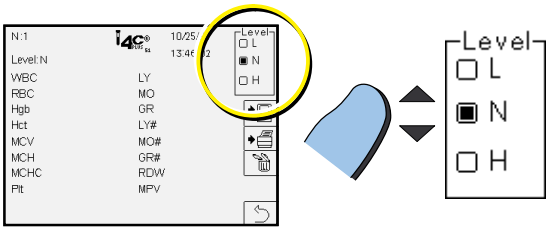


6 Select the correct control level:

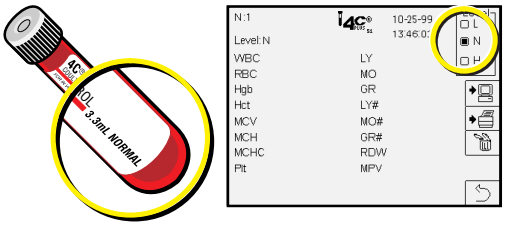
L - for low
N - for normal
H - for high

The square darkens next to your selection.

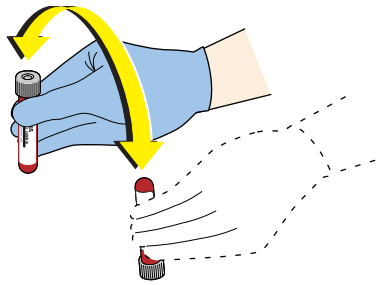
If the selected control level has expired, the **Control Expired** icon appears in the lower left corner of the screen.



7 Make sure that the level of control you are testing matches the one selected (**L**, **N**, or **H**).



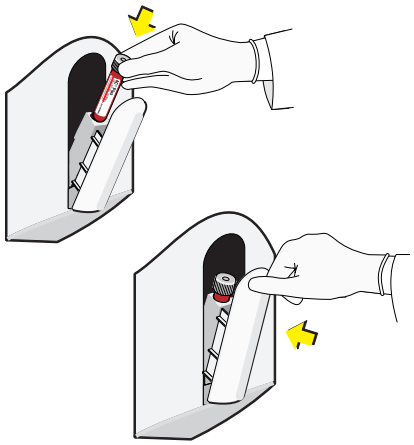
8 Invert the tube once or twice prior to cycling.



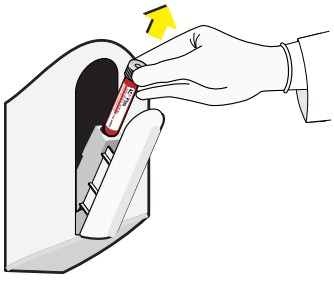
IMPORTANT Risk of misleading results if Cap Pierce Station door is open before the sample analysis is completed. Do not open the door. The door will open automatically.

9 Place the well-mixed sample in the tube holder at the Cap Pierce Station and close the door.

Note: If the door is inadvertently closed after it has opened automatically, or if it is closed at a screen where samples are not run, you can open the door by returning to the Main Menu screen and then touching the **Sample Results** icon. After opening the door, return to the Main Menu screen then return to step 4.

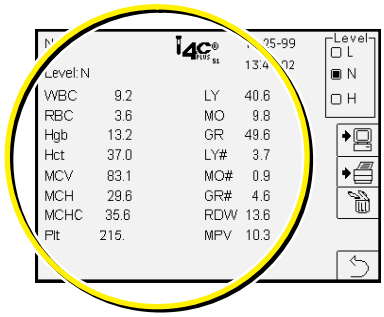


10 When the tube holder door opens, remove the vial and return it to the refrigerator.



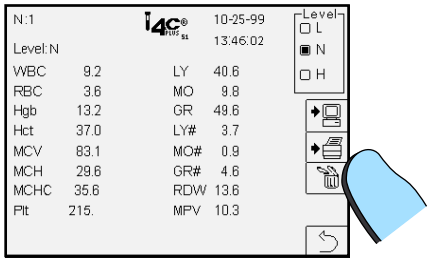
11 Results appear on the screen.

- Unless non-numeric results occur for one or more parameters, the control results are automatically stored.



- If Autoprint is off, you can manually print the results.

- To manually reject these results, touch the **Trash** icon.



- See Special Procedures and Troubleshooting in this manual for information on reviewing flagged results.
- If results are not within the expected range, rerun the control starting at step 7.
- If results are still out of range, see Special Procedures and Troubleshooting in this manual.

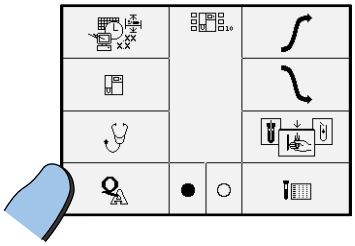
12 Repeat steps 6 through 11 for each required control level.

13 If the results are within the expected range, you are finished running controls.

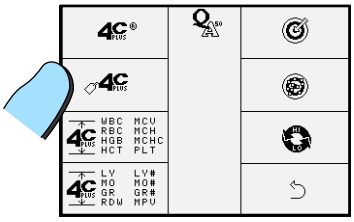
If you do all of the above steps and the results still do not meet your performance expectations, call your local Beckman Coulter Representative.

Printing Stored 4C PLUS Cell Control Results

1 At the Main screen, touch the **QA** icon.



2 At the QA screen, touch the **4C PLUS Management** icon.

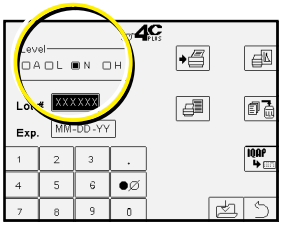


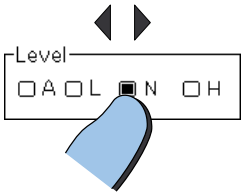
3 Select the control level you want to print:

- **A** = all
- **L** = low
- **N** = normal
- **H** = high

The square darkens next to your selection.

Note: If you are using a ticket printer, you cannot select level **A**.





4 Touch the appropriate **Print** icon for the data you want:

- Touch the **Print** icon to print the assay values currently in the system.

- Touch the **Print Summary** icon to print a summary of the control data.

- If you have a graphic printer, touch the **Graph** icon to print a Levey-Jennings graph of the control data.

2.3 RUNNING LIN-C® LINEARITY CONTROL

The procedure for running LIN-C linearity control is provided below. For all other information regarding LIN-C linearity control, refer to the package insert.

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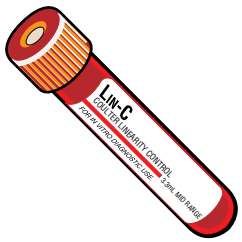
1 Remove the LIN-C linearity controls from the refrigerator and warm at ambient room temperature for 15 minutes.



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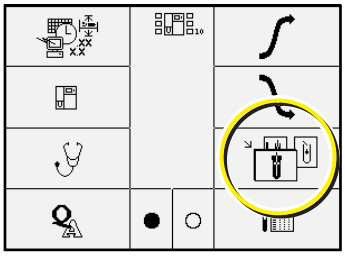
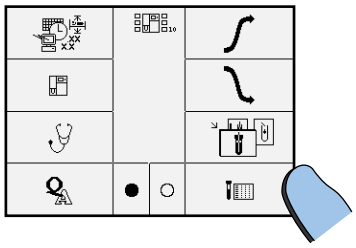
2 At the Main screen, select **Closed Vial Whole Blood** mode.



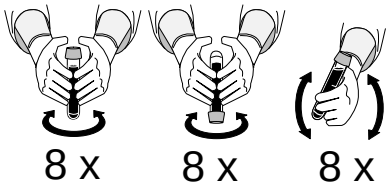
---

3 At the Main screen, touch the **Sample Results Screen** icon.

Note: If the door is inadvertently closed after it has opened automatically, or if it is closed at a screen where samples are not run, you can open the door by touching the **Main Menu** icon and then the **Sample Results** icon.



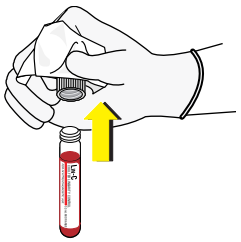
4 Gently mix the control.



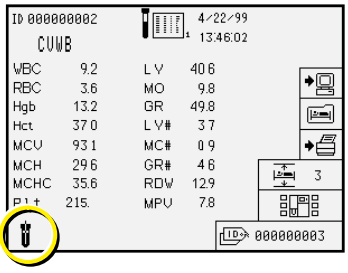
5 Inspect the tube contents to ensure complete resuspension of the contents.

If contents are not uniformly resuspended, repeat step 4.

6 Place a lint-free tissue over the top and remove the cap.



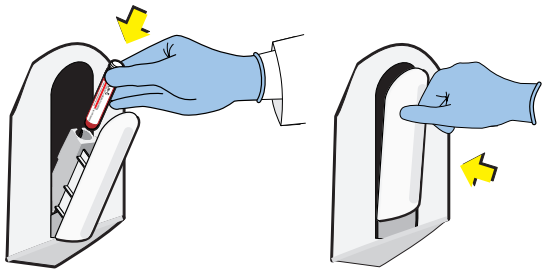
7 Be sure you are in the **Closed Vial Whole Blood** mode.



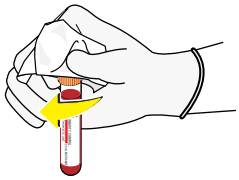
IMPORTANT Risk of misleading results if Cap Pierce Station door is open before the sample analysis is completed. Do not open the tube holde The tube holder will open automatically.

8 Place the well-mixed control in the tube holder at the Cap Pierce Station and close the door.

Note: If the door is inadvertently closed after it has opened automatically, or if it is closed at a screen where samples are not run, you can open the door by touching the **Main Menu** icon and then the **Sample Results** icon.

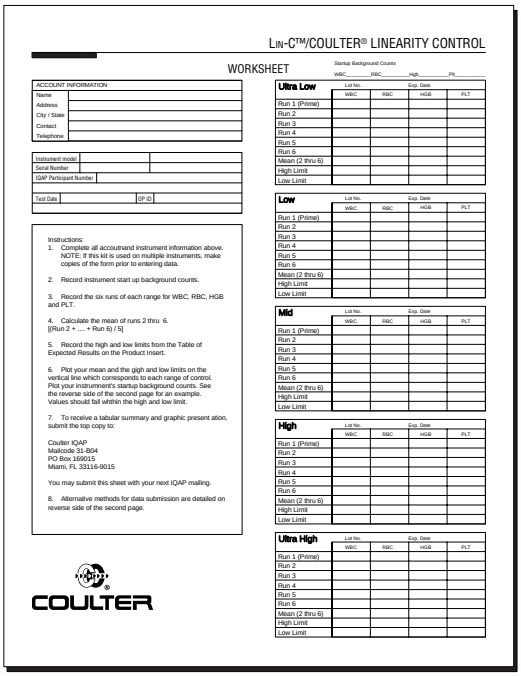


9 Replace the cap securely on the vial.



10 Record the results for WBC, RBC, Hgb, and Plt parameters on the Worksheet. Repeat flagged samples with non-numeric results.

Note: Coulter recommends that five sample results be used to calculate the mean value. A minimum of three samples must be used to calculate the mean when repetitive results with non-numeric values occur.



LIN-C™/COULTER® LINEARITY CONTROL

WORKSHEET

Startup Background Counts
WBC_____ RBC_____ Hgb_____ Plt_____

ACCOUNT INFORMATION

Name	
Address	
City / State	
Contact	
Telephone	

Instrument model		
Serial Number		
IQAP Participant Number		

Test Date _____ OP ID _____

Instructions:
1. Complete all accoutnand instrument information above. NOTE: If this kit is used on multiple instruments, make copies of the form prior to entering data.
2. Record instrument start up background counts.
3. Record the six runs of each range for WBC, RBC, HGB and PLT.
4. Calculate the mean of runs 2 thru 6. [(Run 2 + ... + Run 6) / 5]
5. Record the high and low limits from the Table of Expected Results on the Product Insert.
6. Plot your mean and the gigh and low limits on the vertical line which corresponds to each range of control. Plot your instrumment's startup background counts. See the reverse side of the second page for an example. Values should fall whthin the high and low limit.
7. To receive a tabular summary and graphic present ation, submit the top copy to:

Coulter IQAP
Mailcode 31-B04
PO Box 169015
Miami, FL 33116-9015

You may submit this sheet with your next IQAP mailing.

8. Alternative methods for data submission are detailed on reverse side of the second page.

COULTER

Ultra Low	Lot No.	Exp. Date		
	WBC	RBC	HGB	PLT
Run 1 (Prime)				
Run 2				
Run 3				
Run 4				
Run 5				
Run 6				
Mean (2 thru 6)				
High Limit				
Low Limit				

Low	Lot No.	Exp. Date		
	WBC	RBC	HGB	PLT
Run 1 (Prime)				
Run 2				
Run 3				
Run 4				
Run 5				
Run 6				
Mean (2 thru 6)				
High Limit				
Low Limit				

Mid	Lot No.	Exp. Date		
	WBC	RBC	HGB	PLT
Run 1 (Prime)				
Run 2				
Run 3				
Run 4				
Run 5				
Run 6				
Mean (2 thru 6)				
High Limit				
Low Limit				

High	Lot No.	Exp. Date		
	WBC	RBC	HGB	PLT
Run 1 (Prime)				
Run 2				
Run 3				
Run 4				
Run 5				
Run 6				
Mean (2 thru 6)				
High Limit				
Low Limit				

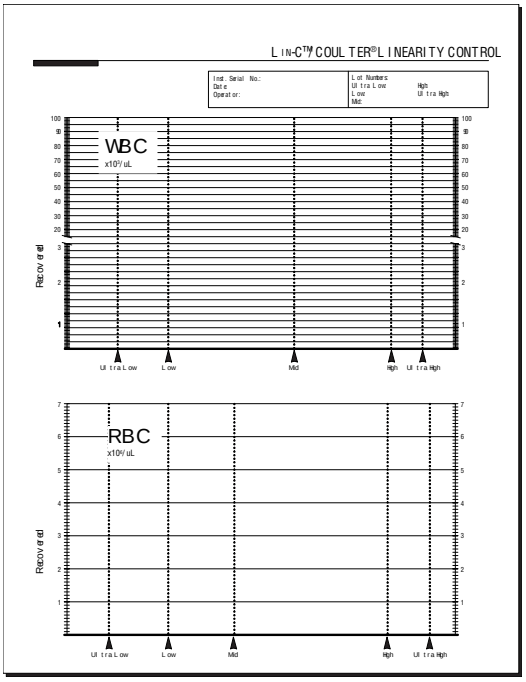
Ultra High	Lot No.	Exp. Date		
	WBC	RBC	HGB	PLT
Run 1 (Prime)				
Run 2				
Run 3				
Run 4				
Run 5				
Run 6				
Mean (2 thru 6)				
High Limit				
Low Limit				

11 Repeat steps 4 through 9 five more times for a total of six runs.

12 Delete the first sample result.

13 Calculate the mean from the last five sample results.

14 Plot the mean recovered values on the LIN-C linearity control graphs.



15 Compare the mean value to the linearity control ranges listed on the Table of Expect Results in your package insert.

16 Plot your instrument's Startup background count results as a zero value on the control graphs to extend the reportable range.

17 Submit your Worksheet data to Coulter's IQAP departments at the address on the Worksheet.

After you submit your data, Coulter prepares tabular summaries and graphic presentations of your data.

2.4 DOWNLOADING 4C PLUS CELL CONTROL RESULTS FOR IQAP

Stored control results can be returned to Coulter for inclusion in the IQAP program. Submit your IQAP data to Coulter each month after completing your last set of controls. For additional information on the IQAP program, see the Reference manual.

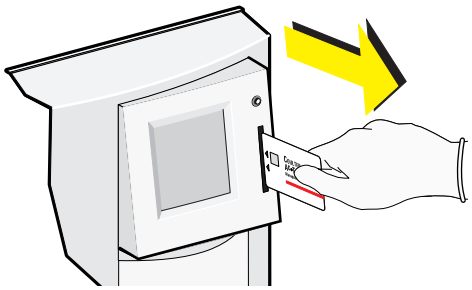
Note: Prior to downloading your data, ensure that your IQAP ID has been entered into your instrument. Without the IQAP ID, your data cannot be automatically processed. Refer to the Installation and Training Guide for information on entering your IQAP ID.

Save used reagent management cards to use for this procedure. A card is ready for use for IQAP when you see this icon appear on your instrument:

Apply the IQAP identification label to a usedreagent management card, using care not to cover up the microchip (gold square).

---

1 Remove the current A^{C}•T diff reagent management card and insert a used reagent management card into the instrument.



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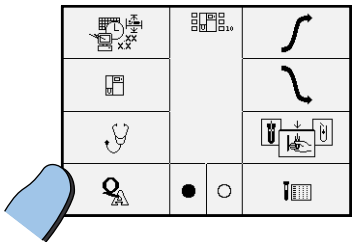
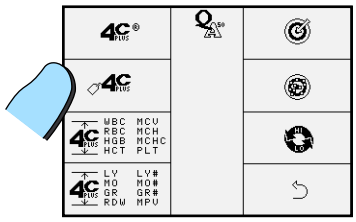
2 At the Main screen, touch the **QA** icon.



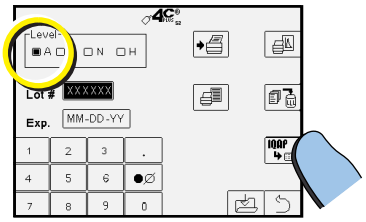
3 At the QA screen, touch the **4C PLUS Management** icon.



4 At the 4C Management screen:

a. Select **A** for all levels of control.

b. Touch the **IQAP** icon to download (send) the data to the card.



5 Touch the **Print Summary** icon to print the control summaries. Keep a copy of the control file data, if possible, for your records.

Note: If you are unable to download the data, submit your control data using a form approved by Coulter's IQAP department.

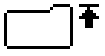
6 Place the following items into the mailer:

- Reagent card with stored control data and attached label
- Copy of the control data.

Return the mailer to Coulter IQAP department.

Note: At the time of enrollment in Coulter's IQAP program, you were supplied with pre-addressed mailers and self-adhesive return labels with your IQAP number. If you need additional information, contact your local Beckman Coulter Representative.

2.5 DELETING 4C PLUS CELL CONTROL FILES

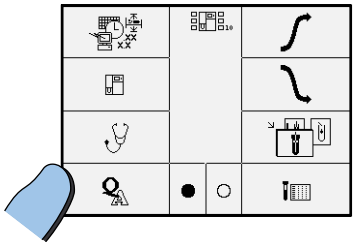
 indicates that one or more of your 4C PLUS cell control files are full and the instrument cannot store any additional control information. If you want to delete existing control files, follow this procedure.

Once deleted, the control files cannot be recovered. Therefore, be sure that you have all the control information you need before deleting anything.

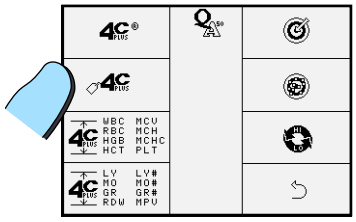
1 If your laboratory is an IQAP participant, download all the control data before proceeding to step 2. See Heading 2.4 for details.

If your laboratory is not an IQAP participant, go to step 2 below.

2 At the Main screen, touch the **QA** icon.



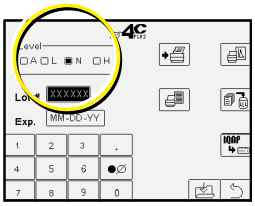
3 At the QA screen, touch the **4C PLUS Management** icon.

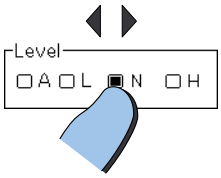


4 Select the control level you want to print.

- **A** = all
- **L** = low
- **N** = normal
- **H** = high

The square darkens next to your selection.





5 Print any control summaries or graphs needed for your records.

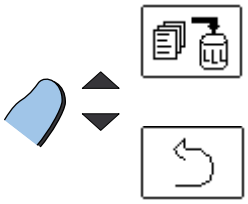
- To print a summary, touch the **Print Summary** icon.

- To print a graph, touch the **Print Graph** icon.

6 Touch the **Trash** icon to delete the control files for the level of control you selected in step 4.

7 The Delete Confirmation screen appears.

- Touch the **Trash** icon to delete
- Touch the **Return** icon to return to the previous screen without deleting.



3.1 GENERAL

When the A^{C}•T diff 2 analyzer is set to the correct analyzing mode (Closed Vial Whole Blood, Open Vial Whole Blood, or Predilute), and you have verified the sample ID, you are ready to run samples.

You can analyze and print sample results with an associated range (**1**, **2**, or **3**). You can also elect to print sample results using the instrument's linearity range (**0**). **Displayed and printed results will be flagged based on the range selected when the sample was run.**

To ensure that the blood specimen is analyzed correctly, you must set the instrument to the correct analyzing mode.

When storing samples:

- Do not refrigerate samples for Platelet and differential counts.
- If you do not need Platelet or differential results, you can store whole-blood specimens drawn in a salt of EDTA at 2 to 8°C.
- Warm samples to room temperature before you cycle them.

To record the sample results correctly, you must ensure that the ID number is correct.

IMPORTANT Risk of misleading results. Running a blood sample in an incorrect analyzing mode can cause wrong results. Only run a whole blood sample in the Whole Blood mode.

Coulter suggests that:

- You analyze a whole blood sample within 24 hours of collection.
- You analyze samples at the system's operating temperature (16-35°C).
- You warm samples to room temperature before you analyze them.
- If flags appear for a sample, you refer to Table 6.4.

3.2 RUNNING WHOLE BLOOD SAMPLES

You can run whole blood samples in the Closed Vial Whole Blood (CVWB) mode or the Open Vial Whole Blood (OVWB) mode. When running samples in the CVWB mode, you leave the cap on the sample tube. When running samples in the OVWB mode, you remove the cap from the sample tube.

Note: You can run open vial samples in the Closed Vial Whole Blood mode. Refer to the procedure entitled Sample Analysis: Open Vial Samples in the Closed Vial Whole Blood Mode.

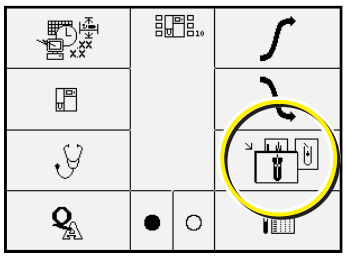
Sample Analysis: Closed Vial Whole Blood Mode

---

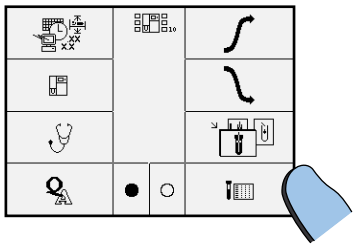
1 Be sure the tubes and/or tube adapters you are using comply with those listed in Appendix B of this manual.

---

2 At the Main screen, select **Closed Vial Whole Blood** mode.

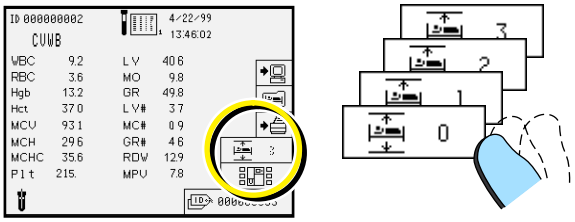


3 At the Main screen, touch the **Sample Results Screen** icon.



Note: If the door is inadvertently closed after it has opened automatically, or if it is closed at a screen where samples are not run, you can open the door by touching the **Main Menu** icon and then the **Sample Results** icon.

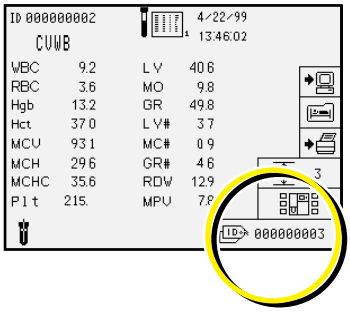
4 Touch the Patient Range icon until the desired range (**1**, **2**, or **3**) appears.



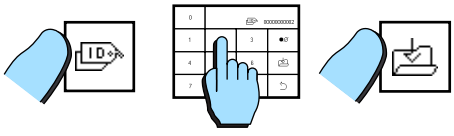
Note: **0** is not a patient range; it is the instrument's linearity limit.

5 Verify that the sample ID is correct:

- If autosequencing is on, the 9-digit sample ID number automatically increments by 1.

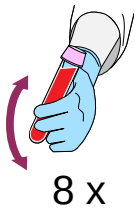


- If autosequencing is off, manually enter the sample ID and touch the **Save** icon. Be careful not to duplicate an existing sample ID number that may have been previously autoincremented.

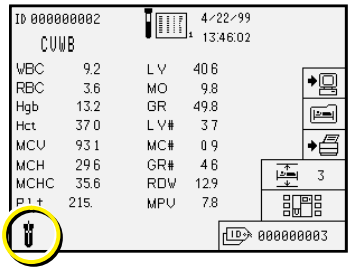


Note: If you try to run another sample using the same ID, a warning will be displayed as a reminder to enter another ID.

6 Mix the sample according to your laboratory's protocol.



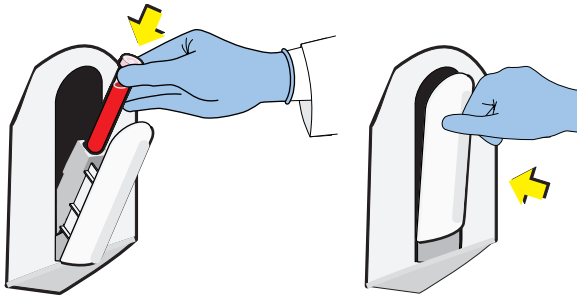
7 Be sure you are in the **Closed Vial Whole Blood** mode.



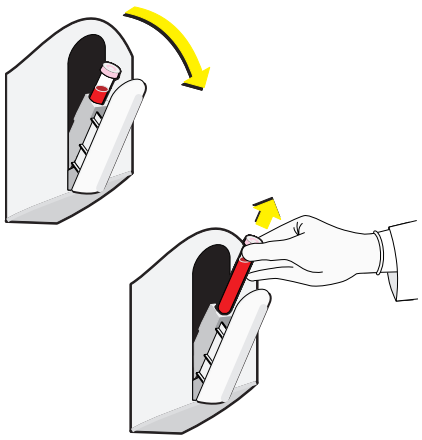
IMPORTANT Risk of misleading results if Cap Pierce Station door is open before the sample analysis is completed. Do not open the tube holder. The tube holder will open automatically.

8 Place the well-mixed sample in the tube holder at the Cap Pierce Station and close the door.

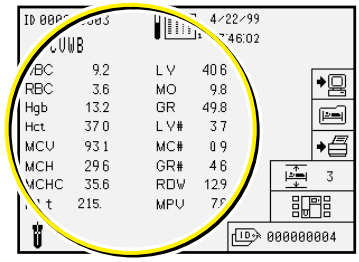
Note: If the door is inadvertently closed after it has opened automatically, or if it is closed at a screen where samples are not run, you can open the door by touching the **Main Menu** icon and then the **Sample Results** icon.



9 When the tube holder door opens, remove the tube.



10 The sample results are automatically saved by the instrument and the results appear on the screen.



11 Print the results:

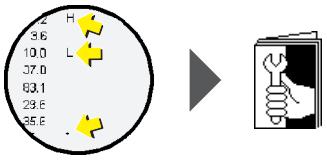
- If Autoprint is on, the results print automatically.
- If Autoprint is off, touch the **Print** icon.

If the printout is illegible, unclear, or incomplete, correct the printer problem and reprint.

12 If autosequence is on, the instrument is ready to run the next sample.

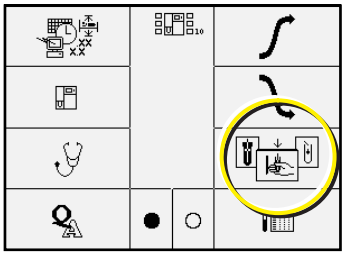
If autosequence is off, you must manually enter an ID number before the probe descends for the next sample.

If flags appear, see Special Procedures and Troubleshooting in this manual.

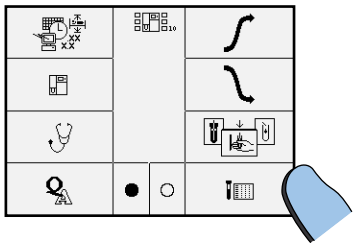


Sample Analysis: Open Vial Whole Blood Mode

1 At the Main screen, select **Open Vial Whole Blood** mode.

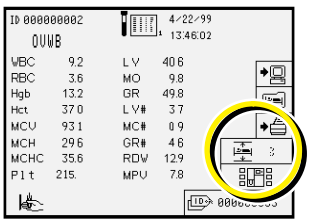


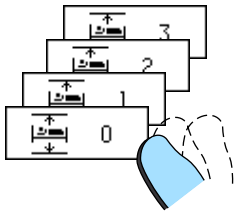
2 At the Main screen, touch the **Sample Results Screen** icon.



3 Touch the Patient Range icon until the desired range (**1**, **2**, or **3**) appears.

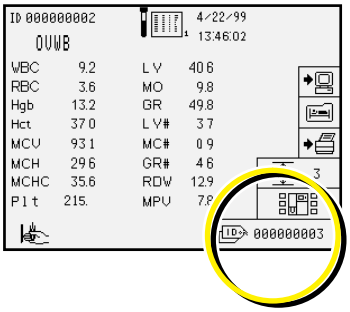
Note: **0** is not a patient range; it is the instrument's linearity limit.



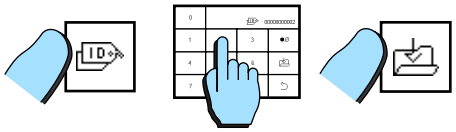


4 Verify that the sample ID is correct:

- If autosequencing is on, the sample ID number automatically increments by 1.

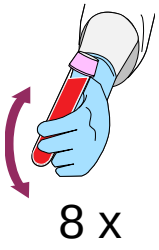


- If autosequencing is off, manually enter the sample ID and touch the **Save** icon. Be careful not to duplicate an existing sample ID number that may have been previously autoincremented.

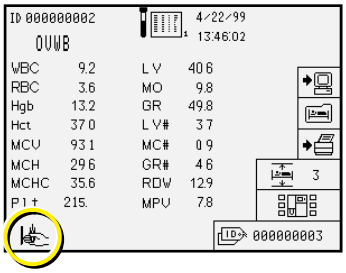


Note: If autosequencing is off, the probe does not descend until you manually enter and save the next ID.

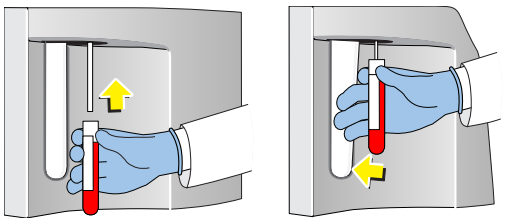
5 Mix the sample according to your laboratory's protocol, and place a lint-free tissue over the top and remove the cap.



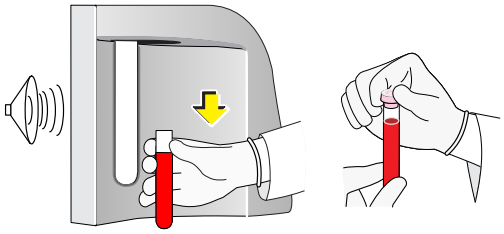
6 Be sure you are in the **Open Vial Whole Blood** mode.



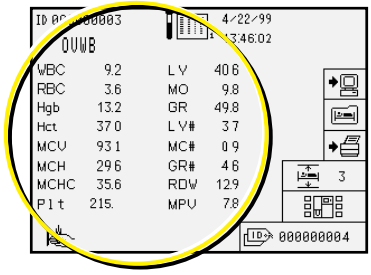
7 Present the well-mixed sample to the probe so that the tip is well into the tube, and press the aspirate switch.



8 When you hear the beep, remove the sample, and put the cap back on the tube.



9 The sample results are automatically saved by the instrument, and the results appear on the screen.



10 Print the results:

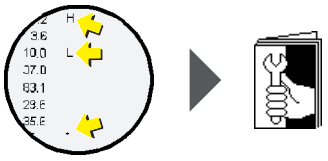
- If Autoprint is on, the results print automatically.
- If Autoprint is off, touch the **Print** icon.

If the printout is illegible, unclear, or incomplete, correct the printer problem and reprint.

11 If autosequence is on, the instrument is ready to run the next sample.

If autosequence is off, you must manually enter an ID number before the probe descends for the next sample.

If flags appear, see Special Procedures and Troubleshooting in this manual.



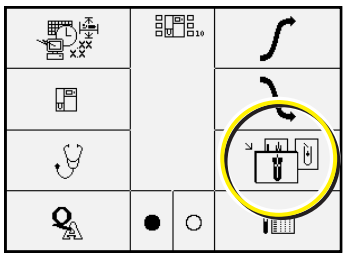
Sample Analysis: Open Vial Samples in the Closed Vial Whole Blood Mode

You can analyze an open vial (uncapped) sample in the Closed Vial Whole Blood mode.

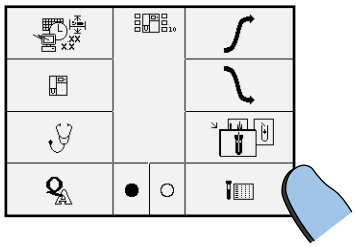
WARNING Risk of biohazard condition. The level of the vial contents must be at least a half inch below the top of the vial when running an uncapped (open vial) sample in the Closed Vial Whole Blood mode.

1 Be sure the tubes and/or tube adapters you are using comply with those listed in Appendix B of this manual.

2 At the Main screen, select **Closed Vial Whole Blood** mode.

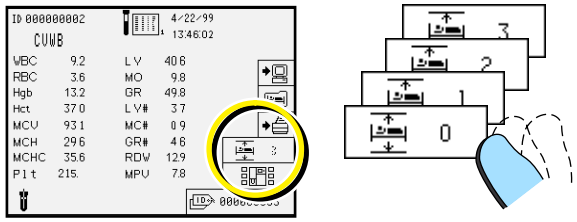


3 At the Main screen, touch the **Sample Results Screen** icon.



Note: If the door is inadvertently closed after it has opened automatically, or if it is closed at a screen where samples are not run, you can open the door by going touching the **Main Menu** icon and then the **Sample Results** icon.

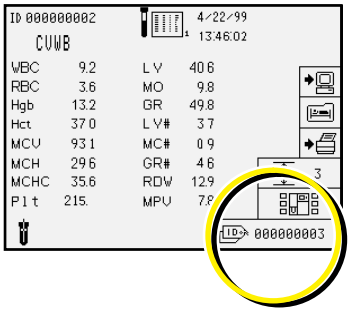
4 Touch the Patient Range icon until the desired range (**1**, **2**, or **3**) appears.



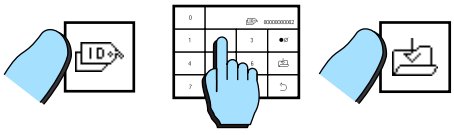
Note: **0** is not a patient range; it is the instrument's linearity limit.

5 Verify that the sample ID is correct:

- If autosequencing is on, the sample ID number automatically increments by 1.



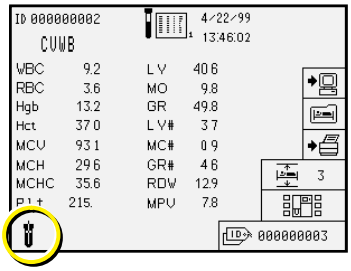
- If autosequencing is off, manually enter the sample ID and touch the **Save** icon. Be careful not to duplicate an existing sample ID number that may have been previously autoincremented.



Note: If you try to run another sample using the same ID, a warning will be displayed as a reminder to enter another ID.

6 Mix the sample according to your laboratory's protocol.

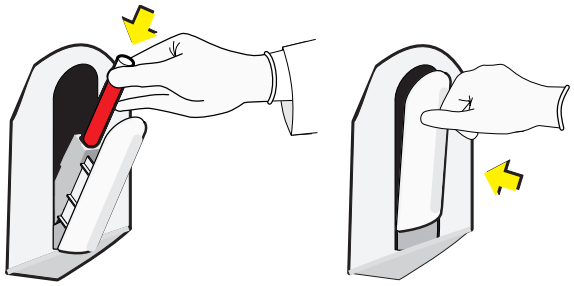
7 Be sure you are in the **Closed Vial Whole Blood** mode.



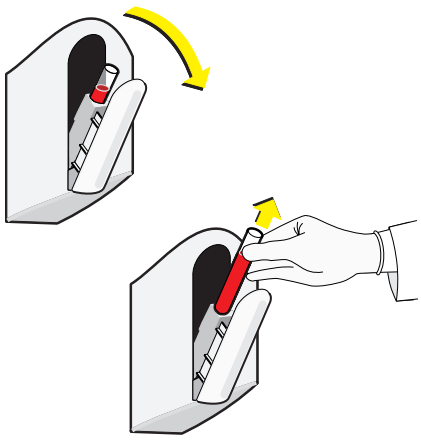
IMPORTANT Risk of misleading results if Cap Pierce Station door is open before the sample analysis is completed. Do not open the tube holder. The tube holder will open automatically.

8 Place the well-mixed sample in the tube holder at the Cap Pierce Station and close the door.

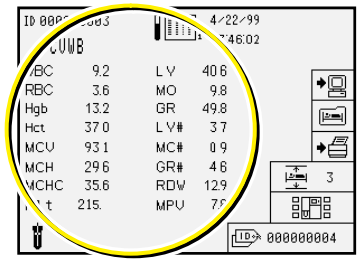
Note: If the door is inadvertently closed after it has opened automatically, or if it is closed at a screen where samples are not run, you can open the door by going touching the **Main Menu** icon and then the **Sample Results** icon.



9 When the tube holder door opens, remove the tube.



10 The sample results are automatically saved by the instrument and the results appear on the screen.



11 Print the results:

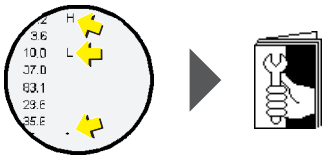
- If Autoprint is on, the results print automatically.
- If Autoprint is off, touch the **Print** icon.

If the printout is illegible, unclear, or incomplete, correct the printer problem and reprint.

12 If autosequence is on, the instrument is ready to run the next sample.

If autosequence is off, you must manually enter an ID number before the tube holder door opens for the next sample.

If flags appear, see Special Procedures and Troubleshooting in this manual.



3.3 RUNNING PREDILUTED BLOOD SAMPLES

If it is your laboratory's procedure to collect specimens for hematology via capillary collection into a microcollection device, you may run the specimen in the whole blood mode. However, the Predilute mode should be used if the specimen collected cannot be directly aspirated in a whole blood mode.

The Predilute mode dispenses 1580 µL of diluent into an empty tube or receptacle where 20 µL of capillary blood will be added, thereby diluting it, to create an adequate amount of sample volume for the instrument to aspirate for analysis.

IMPORTANT Risk of misleading results. Running a blood sample in an incorrect analyzing mode can cause wrong results. Only run prediluted blood in the Predilute mode.

Coulter suggests that:

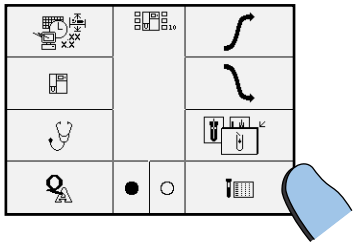
- You analyze prediluted specimens for CBC within 4 hours of collection/preparation.
- You analyze prediluted specimens for diff within 1 hour of collection/preparation.
- You allow a prediluted sample to stabilize in the predispensed diluent for at least 5 minutes.
- If flags appear, you refer to Special Procedures and Troubleshooting in this manual.
- You analyze at system operating temperature (16-35°C).
- Each laboratory evaluate predilute stability based on their sample population and specimen collection techniques or methods.

Note: Prediluted samples require analysis in the Predilute mode.

1 At the Main screen, select the **Predilute** mode.

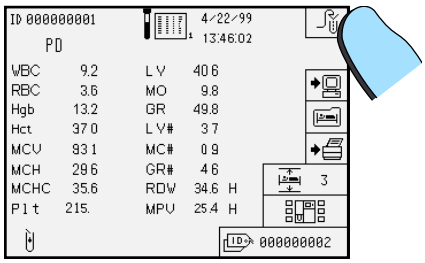
2 At the Main screen, touch the **Sample Results Screen** icon.

- If preparing prediluted samples, do steps 3 through 5.
- If dilutions are already prepared, go to step 7.



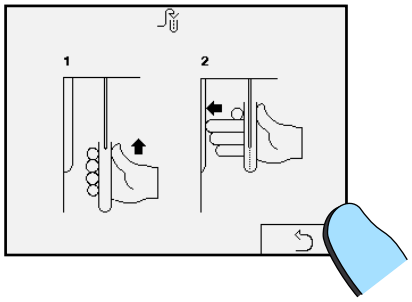
3 Touch the **Dispense Diluent** icon.

The aspiration probe then retracts into the instrument and descends again.



4 Present an empty tube to the probe and press the aspirate switch to dispense 1580 µL of diluent into the empty tube.

When all your samples are prepared, touch the **Exit** icon to return to the Sample Results Screen.

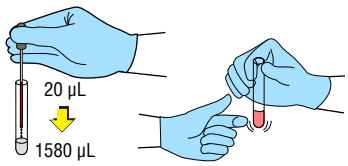


5 Prepare the sample for analysis:

a. Add 20 µL of blood specimen to the diluent in the tube.

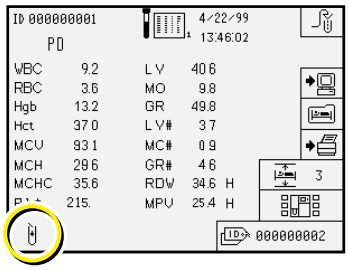
b. Mix the sample according to your laboratory's protocol.

c. Wait at least 5 minutes before running the sample.



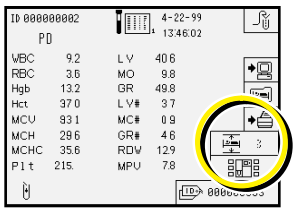
6 Repeat steps 3 through 5 for each sample.

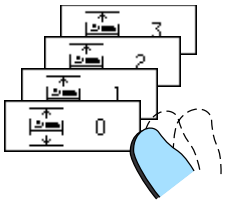
7 Be sure you are in the **Predilute** mode.



8 Touch the **Patient Range** icon until the desired range (**1**, **2**, or **3**) appears.

Note: 0 is not a patient range; it is the instrument's linearity limit.

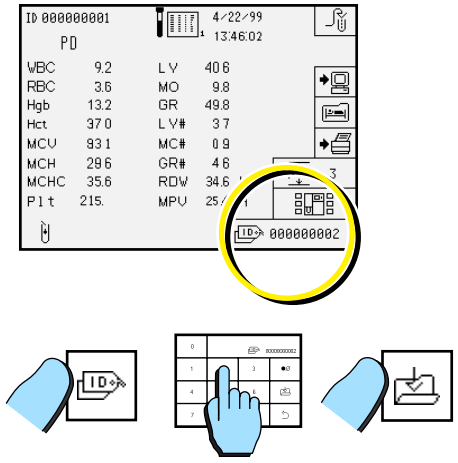




9 Verify that the sample ID is correct:

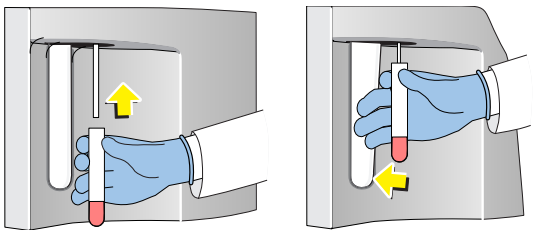
- If autosequencing is on, the sample ID number automatically increments by 1.
- If autosequencing is off, manually enter the sample ID and touch the **Save** icon. Be careful not to duplicate an existing sample ID number that may have been previously autoincremented.

Note: If autosequencing is off, the probe does not descend until you manually enter and save the next ID.

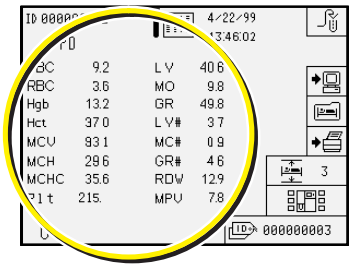


10 Present the well-mixed, prediluted sample to the probe and press the aspirate switch.

When you hear the beep, remove the sample.



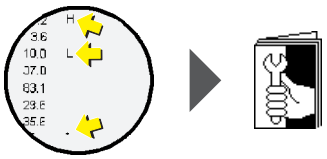
11 The A^{C}•T diff 2 analyzer displays the sample results on the screen and automatically saves them.



12 Print the results:

- If Autoprint is on, the results print automatically.
- If Autoprint is off, touch the **Print** icon.

13 If flags appear, see Special Procedures and Troubleshooting in this manual.



14 If autosequence is on, the instrument is ready to run the next sample.

If autosequence is off, you must manually enter an ID number before the probe descends for the next sample.

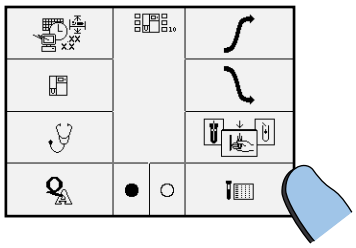
4.1 PRINTING STORED SAMPLE RESULTS

The instrument automatically saves (stores) up to 250 patient results (numerical only, excluding histograms). Results are saved after sample analysis is completed. There may be times when you need to review certain patient results that were saved. You can recall patient results based on the date of analysis. This procedure explains how to do that.

This function is available for use with the graphic printer only.

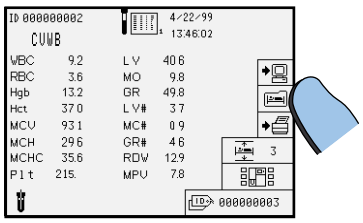
---

1 At the Main screen, touch the **Sample Results Screen** icon.

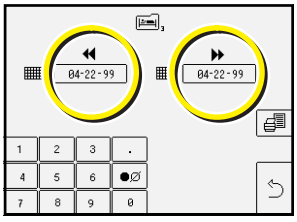


---

2 At the Sample Results Screen, touch the **Retrieve Stored Data** icon.



A screen with date fields appears. The date field on the left is the “from” date field, and the date field on the right is the “to” date field.

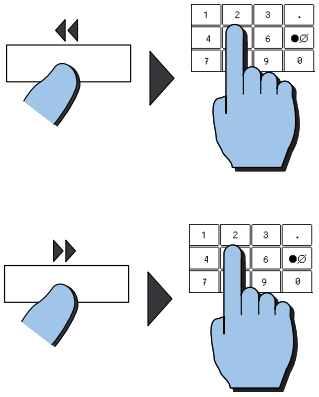


3 Enter the date range of the samples you want to review.

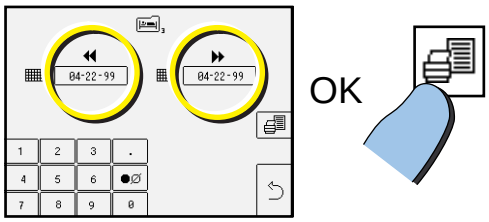
a. Enter the beginning date of the sample results you want.

b. Enter the ending date of the sample results you want.

Note: Be sure to use the dash to separate the month-day-year, such as 01-01-99.

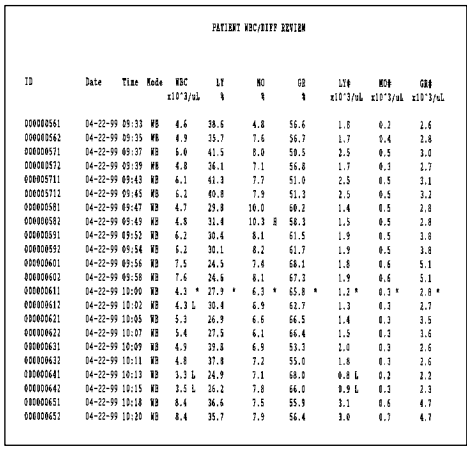


4 Touch the **Print Summary** or **Report** icon to print the results. The **In Progress** icon appears on the screen during printing.



A report prints out similar to that shown here. The report reflects only the sample data saved for only the date range that you entered.

Note: In case of multiple samples with the same sample ID#, use the date and time to differentiate the runs.



PATIENT WBC/DIFF REVIEW

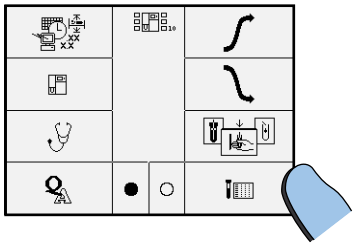
ID	Date	Time	Mode	WBC x10^3/uL	LY %	MO %	GR %	LY# x10^3/uL	MO# x10^3/uL	GR# x10^3/uL
000080561	04-22-99	05:33	WB	4.6	38.6	4.8	56.6	1.8	0.2	2.6
000080562	04-22-99	05:35	WB	4.9	35.7	7.6	56.7	1.7	0.4	2.8
000080571	04-22-99	05:37	WB	5.0	41.5	8.0	50.5	2.5	0.5	3.0
000080572	04-22-99	05:39	WB	4.8	36.1	7.1	56.8	1.7	0.3	2.7
000085711	04-22-99	05:43	WB	4.1	41.3	7.7	51.0	2.5	0.5	3.1
000085712	04-22-99	05:45	WB	5.1	40.8	7.9	51.3	2.5	0.5	3.2
000080581	04-22-99	05:47	WB	4.7	29.8	10.0	60.2	1.4	0.5	2.8
000080582	04-22-99	05:49	WB	4.8	31.4	10.3	H 58.3	1.5	0.5	2.8
000080591	04-22-99	05:52	WB	5.2	30.4	8.1	61.5	1.9	0.5	3.8
000080592	04-22-99	05:54	WB	5.2	30.1	8.2	61.7	1.9	0.5	3.8
000080601	04-22-99	05:56	WB	7.5	24.5	7.8	68.1	1.8	0.6	5.1
000080603	04-22-99	05:58	WB	7.6	24.6	8.1	67.3	1.9	0.6	5.1
000080611	04-22-99	10:00	WB	4.3 *	27.9 *	6.3 *	65.8 *	1.2 *	0.3 *	2.8 *
000080612	04-22-99	10:02	WB	4.3 L	30.4	6.9	62.7	1.3	0.3	2.7
000080621	04-22-99	10:05	WB	5.3	26.9	6.6	66.5	1.4	0.3	3.5
000080622	04-22-99	10:07	WB	5.4	27.5	6.1	66.4	1.5	0.3	3.6
000080631	04-22-99	10:09	WB	4.9	39.8	6.9	53.3	2.0	0.3	2.6
000080632	04-22-99	10:11	WB	4.8	37.8	7.2	55.0	1.8	0.3	2.6
000080641	04-22-99	10:13	WB	3.3 L	24.9	7.1	68.0	0.8 L	0.2	2.2
000080642	04-22-99	10:15	WB	3.5 L	26.2	7.8	66.0	0.9 L	0.3	2.3
000080651	04-22-99	10:18	WB	8.4	36.6	7.5	55.9	3.1	0.6	4.7
000080652	04-22-99	10:20	WB	8.4	35.7	7.9	56.4	3.0	0.7	4.7

Printing Sample Results

You can print sample results with an associated range (**1**, **2**, or **3**). You can also select to print sample results using the instrument's linearity range (**0**). **Displayed and printed results are flagged based on the range selected when the sample was run.**

---

1 At the Main screen, touch the **Sample Results** icon.



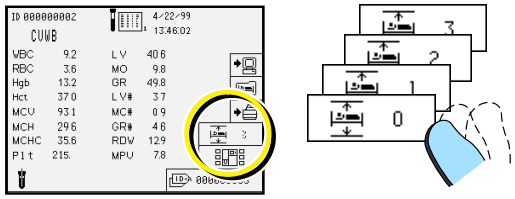
---

2 Touch the **Patient Range** icon until the desired range (**1**, **2**, or **3**) appears.

Note: **0** is not a patient range; it is the instrument's linearity limit.

Flagging of results is done at the time the sample is analyzed. Changing the patient range after the sample was analyzed will not change the flagging.

A new selected patient range will be reflected on the printout only when a new sample is processed.



---

3 Touch the **Print** icon to print.

5.1 OVERVIEW

Coulter calibrates the A^{C}•T diff 2 analyzer at the factory before shipment, and the calibration data is provided with your instrument documentation. You may need to perform calibration procedures when you replace any instrument component that involves the primary measurement characteristics (such as an aperture).

Because the instrument is electronically stable, it should not require frequent recalibration when you operate it and maintain it according to the recommendations in this manual. Make the decision to recalibrate based on the performance of your quality control program.

Coulter recommends that you calibrate your instrument according to the regulations required by your inspecting agency.

Your laboratory's quality control program should continually monitor and confirm instrument calibration. Review your control results periodically. Keep a written record of this review. To confirm calibration of the A^{C}•T diff 2 analyzer:

1. Verify that 95% of control results are within their ranges as listed in the TABLE OF EXPECTED RESULTS.
2. Verify that there are no unexplained shifts or trends in the data.

If recalibration appears necessary, but you have not replaced a component affecting calibration, do **NOT** recalibrate the instrument.

1. First, thoroughly clean your analyzer following the Clean the Baths procedure in Chapter 6 of this manual.
2. Then reanalyze a new vial of control material.
   - If the control results are still outside of the expected ranges, refer to Table 6.10 and Heading 6.12 in this manual.
   - If the results remain outside the expected ranges, call your Beckman Coulter Representative before recalibrating.

When necessary, perform calibration by following the procedures given in this section.

Before you begin calibration, be sure you have enough reagents to perform the complete procedure. If you run out of reagents during calibration, you must start over and perform a complete calibration.

Recommended Calibrator

Coulter recommends using S-CAL calibrator for automated calibration. If S-CAL calibrator is not available, manual calibration can be done after Reproducibility and Carryover are completed. See Appendix A for the manual calibration procedure.

You can calibrate either automatically or manually, using S-CAL calibrator.

5.2 BEFORE CALIBRATING

Before calibrating, you must first prepare the instrument:

1. Do Heading 5.3, PRECALIBRATION CHECKS.
2. Do Heading 5.4, REPRODUCIBILITY.
3. Do Heading 5.5, CARRYOVER.

5.3 PRECALIBRATION CHECKS

1 Be sure that all required maintenance (including replacement of parts) has been performed on the instrument. See Special Procedures and Troubleshooting in this manual.

2 Do the Clean the Baths procedure in Chapter 6 of this manual.

3 Calibrate only when the ambient temperature is within the system's operating range (20-35° C).

4 Check that you have a sufficient supply of reagents to complete this procedure.

5 Perform Startup in Heading 1.1 of this manual.

5.4 REPRODUCIBILITY

The A^{C}•T diff 2 analyzer includes a Reproducibility function that automatically performs calculations on the samples you run.

Reproducibility is a check to ensure that the instrument measures blood parameters consistently and precisely. After you run the sample N times consecutively, the instrument:

- Calculates the SD of *N* results of the sample.
- Calculates the mean coefficient of variation (%CV) and standard deviation (SD) for the parameters
- Prints *PASS* or *FAIL* message for the reproducibility test.

You can run reproducibility in any of the following modes:

- Whole Blood (Closed Vial or Open Vial)
- Predilute

It is recommended that you run Reproducibility in the Whole Blood mode using either whole blood or a cell control with a known range of values, such as 4C PLUS cell control.

To perform statistics, the instrument requires a minimum of three acceptable samples. If a numeric result is not acceptable, the instrument automatically rejects the result. You can also reject a result by touching the **Reject** icon.

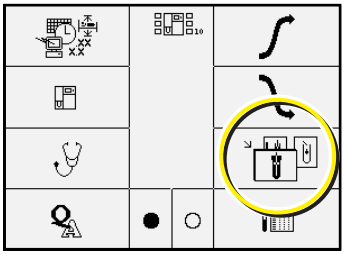
There is a summary screen for Reproducibility. Autoprint, if turned ON, prints a sample report upon completion of each run. Autoprint is not an option for printing the summary report; you must manually select the print summary icon. You can print a summary report beginning with the third sample all the way to the thirty-first sample, if you choose to run that many samples.

Note: When doing Reproducibility, Carryover, or Calibration, do not leave the screen until you finish analyzing the required number of samples. Leaving the screen without finishing the required analysis will delete your data, which means that you must restart the test.

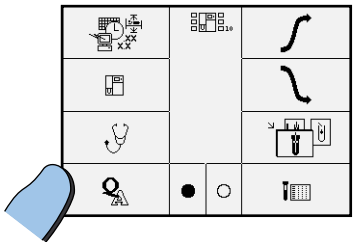
1 Select a sample that meets these parameter criteria:

WBC at 6.0 - 15.0 x 10^3 cells/µL
RBC at 3.00 - 6.00 x 10^6 cells/µL
Hgb at 12.0 - 18.0 g/dL
MCV at 80.0 - 100.0 fL
Plt at 200 - 500 x 10^3 cells/µL

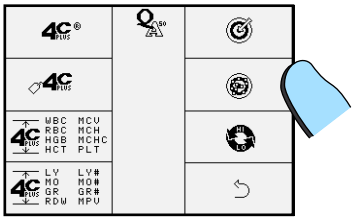
2 At the Main screen, select the desired mode to run normal samples or 4C PLUS cell control.



3 At the Main screen, touch the **QA** icon.

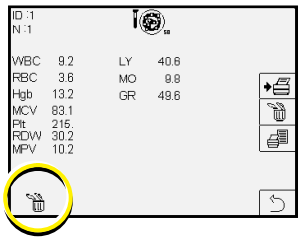


4 At the QA screen, touch the **Reproducibility** icon.



5 Analyze the sample based on the mode you selected in step 2.

If a non-numeric result is obtained or if you manually reject the sample, the **Trash** icon appears in the lower left corner of the screen.



6 When the sample result is displayed, touch the **Trash** icon to manually delete the first (prime) sample.

7 Repeat step 5 until an N of 10 is achieved. Look at the upper left corner of the screen for the N#.

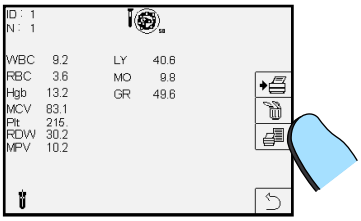
After the instrument accepts the data, the Reproducibility results are stored.

Note: Up to 31 samples can be run as part of the statistical calculations.

8 If you are using a graphic printer, touch the **Print Summary** icon.

The Reproducibility Summary Report prints similar to that shown below. Keep a copy for your records.

Note: A minimum of two samples is needed to print a sample summary.



REPRODUCIBILITY

CVWB
Date: 10-13-99 Time: 11:35

REPRODUCIBILITY RESULTS

N	WBC	LY	MO	GR	RBC	HGB	MCV	PLT	RDW	MPV
1	4.89	41.50	5.00	53.50	4.786	13.48	86.29	209.9	13.28	8.45
2	5.02	41.20	5.50	53.30	4.836	13.50	86.55	198.0	12.53	8.45
3	5.11	41.80	5.20	53.00	4.919	13.79	86.73	213.8	13.22	8.65
4	5.04	41.10	6.30	52.60	4.961	13.74	85.85	202.2	12.87	8.84
5	5.04	40.40	7.30	52.30	4.940	13.88	85.49	199.0	13.16	8.65
6	5.09	41.30	6.50	52.20	4.898	13.87	85.77	206.6	13.10	8.65
7	5.11	40.10	6.30	53.60	4.879	13.66	85.97	198.1	12.75	8.45
8	5.08	40.00	7.60	52.40	4.909	13.82	86.09	199.3	13.21	8.55
9	5.13	41.20	6.90	51.90	4.916	13.93	85.94	212.3	12.60	8.45
10	5.11	40.80	6.30	52.90	4.894	13.75	86.16	203.3	12.84	8.45
11	5.16	39.00	8.20	52.80	4.865	13.92	86.09	217.1	13.05	8.65

SUMMARY STATISTICS RUNS

Mean	5.09	40.69	6.61	52.70	4.902	13.79	86.06	205.0	12.93	8.58
sd	0.04	0.82	0.92	0.52	0.036	0.13	0.36	7.1	0.25	0.13
%CV	0.87	2.02	13.89	0.99	0.74	0.96	0.42	3.47	1.95	1.53
Status	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED

7495024A

Note: For information on parameter limits, refer to PERFORMANCE SPECIFICATIONS in the Reference manual.

If Reproducibility fails, contact your local Beckman Coulter Representative.

---

9 Do Heading 5.5, CARRYOVER.

5.5 CARRYOVER

Carryover is a check to make sure that no part of a sample is carried over to the next sample, thus affecting the next sample's results. Carryover:

- determines if there is carryover from the sample, and
- prints *PASS* or *FAIL* message for the carryover test.

Note: You may use 4C PLUS cell control as an alternative to normal whole-blood samples.

The instrument determines what is acceptable for carryover.

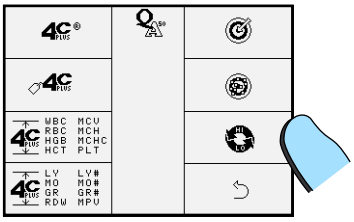
When doing Reproducibility, Carryover, or Calibration, do not leave the screen until you finish analyzing the required number of samples. Leaving the screen without finishing the required analysis will delete your data, which means that you must restart the test.

---

1 Be sure that you completed Reproducibility.

---

2 Touch the **Carryover** icon.



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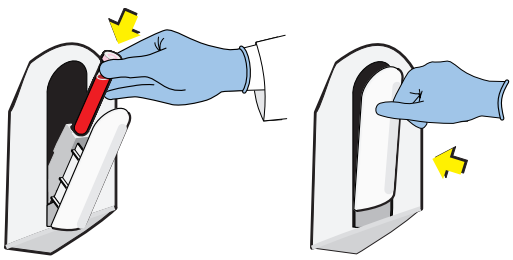
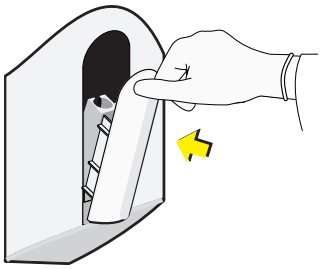
3 Place the well-mixed sample into the tube holder, and close the door.



4 Repeat step 3 for the second sample.

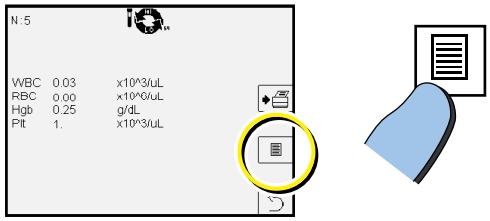
5 Run a blank sample (air) by closing the tube holder.



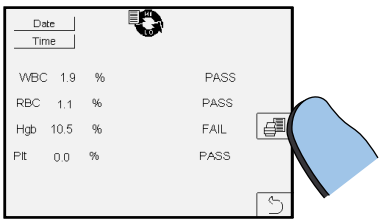
6 Repeat step 5 twice for a total of three blank samples.

7 Touch the **Summary** icon to view the summary screen.

Note: The N# on the screen indicates the numbers of acceptable runs.



8 Touch the **Print Summary** icon to print a summary report for your records.



This is an example of a Carryover Summary Report.

Note: For information on parameter limits, refer to PERFORMANCE SPECIFICATIONS in the Reference manual.

If Carryover fails, contact your local Beckman Coulter Representative.

CARRYOVER

Date: 08-27-97 Time: 09:52

CARRYOVER RESULTS

N	WBC	RBC	HGB	PLT
1	9.0	4.60	13.1	236.
2	9.1	4.71	13.3	251.
3	0.1	0.00	0.0	0.
4	0.1	0.00	0.0	0.
5	0.1	0.00	0.0	0.

Carryover%

0.0	0.0	0.0	0.0

Status

PASSED PASSED PASSED PASSED

9 Do Heading 5.6, AUTO-CALIBRATION.

5.6 AUTO-CALIBRATION

Calibration standardizes the instrument by determining its deviation from calibration references and adjusting calibration factors as needed.

The S-CAL calibration kit helps you determine whether the calibration factors of the instrument need to be changed. Assigned values are provided in the S-CAL calibration kit package insert. **Only the package inserts provided with the S-CAL calibration kit provide the correct assigned values for the calibrator**.

For automated calibration, you simply cycle the S-CAL calibrator in the Closed Vial Whole Blood mode. After you enter the ASSIGNED VALUES from the S-CAL calibrator package insert, calculations and comparisons to assigned values are done automatically by the instrument. You can save the calibration data.

After calibration is completed, a *PASSED, NEEDED* or *FAILED* message appears for each parameter.

When doing Reproducibility, Carryover, or Calibration, do not leave the screen until you finish analyzing the required number of samples. Leaving the screen without finishing the required analysis will delete your data, which means that you must restart the test.

---

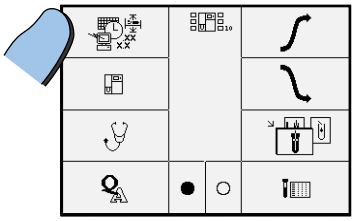
1 Be sure that you completed the Reproducibility and Carryover procedures.

---

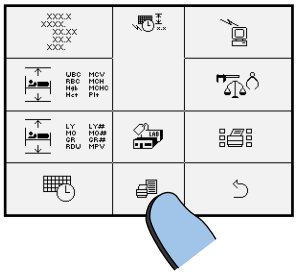
2 Verify that one vial of the S-CAL calibrator is at room temperature.

3 Print the calibration setup report.

a. At the Main screen, touch the **Setup** icon.

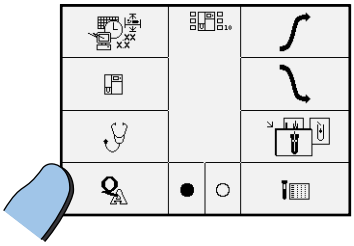


b. At the Setup screen, touch the **Setup Report** icon.

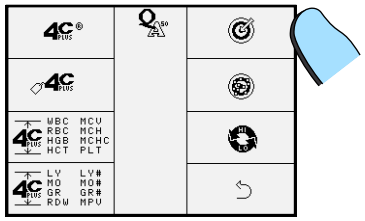


c. After the calibration setup report prints, touch the **Exit** icon.

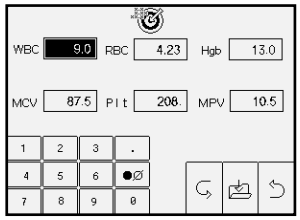
4 At the Main screen, touch the **QA** icon.



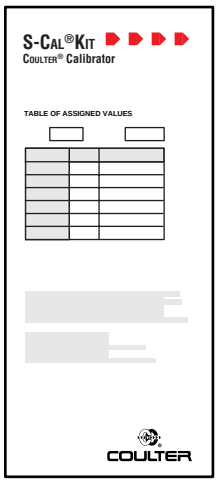
5 At the QA screen, touch the **Calibration** icon.



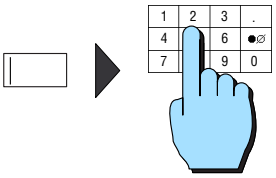
The calibration assay screen appears.



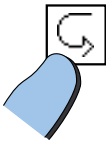
6 Refer to the TABLE OF ASSIGNED VALUES on the S-CAL calibrator package insert.



7 On the screen, touch the field where you want to enter values, and enter the values from the TABLE OF ASSIGNED VALUES using the keypad.



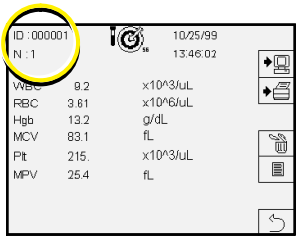
8 Save the values you entered by touching the **Continue** icon.



The run screen appears.

The ID# refers to the number of runs done under this calibration procedure.

The N# refers to the actual number of accepted samples for this test.

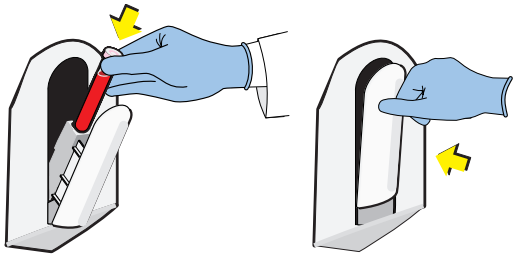


9 Mix the S-CAL calibrator according to the package insert.

10 Pipette the S-CAL calibrator into the empty mixing tube according to the instructions in the package insert.

IMPORTANT Risk of misleading results if Cap Pierce Station door is open before the sample analysis is completed. Do not open the tube holder. The tube holder will open automatically.

11 Place the well-mixed sample in the tube holder at the Cap Pierce Station and close the door.



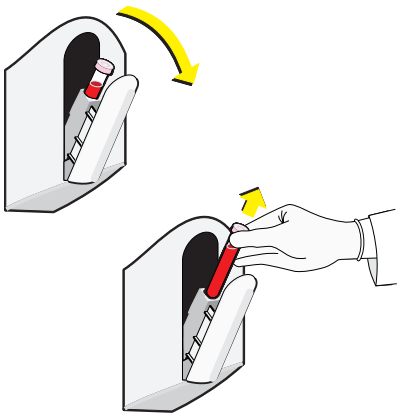
Note: If the door is inadvertently closed after it has opened automatically, or if it is closed at a screen where samples are not run, you can open the door by touching the **Main Menu** icon and then the **Sample Results** icon.

12 When the tube holder opens:

a. Remove the calibrator vial from the holder.

b. Mix the vial gently between each cycle.

c. After analysis is complete, the results of sample #1 appear.



If an Aperture Alert message or any non-numeric result (XXXXX, - - - - -, •••••, +++++) occurs, the results will be displayed but the instrument automatically rejects them.

- If a result is rejected by the instrument, the N# does not increment.
- If you choose to reject the result for the last sample run, the N# automatically decrements by 1. (You can only reject the last sample analyzed.)

13 Repeat steps 11 and 12 for each of the 11 calibration samples.

Note: The instrument does not use results for the first replicate. It performs statistics on replicates 2 through 11 for a total of 10.

The instrument automatically saves the results.

14 Print the results:

- If Autoprint is on, the results print automatically.
- If Autoprint is off, touch the **Print** icon.

15 After 11 acceptable sample results, the **Print Summary** icon appears; touch the icon to view the summary screen.

- If Autoprint is ON and you are using a graphic printer, a summary report prints automatically.
- If autoprint is OFF, you can print a report summary by pressing the **Print Summary** icon.

This is an example of a Calibration Summary Report.

CALIBRATION

Date: 08-27-99 Time: 09:18

N	WBC	RBC	HGB	MCV	PLT	MPV
1	9.13	4.713	13.26	90.89	245.4	10.12
2	8.97	4.634	13.22	90.88	234.8	10.22
3	8.89	4.731	13.36	90.93	251.9	10.22
4	9.02	4.714	13.40	90.49	254.6	10.32
5	9.03	4.676	13.36	90.74	247.1	10.32
6	9.04	4.705	13.29	90.55	249.5	10.22
7	9.19	4.764	13.49	90.52	247.5	10.12
8	9.05	4.692	13.27	90.48	239.3	10.02
9	9.13	4.716	13.41	90.46	247.4	10.22
10	9.10	4.706	13.34	90.59	237.2	10.02
11	9.00	4.635	13.13	90.44	240.6	10.12
MEAN	9.04	4.697	13.33	90.61	245.0	10.18
TARGET	9.2	4.71	13.3	91.0	246.	10.0
CV	0.93	0.86	0.77	0.20	2.70	1.06
%DIFF	1.74	0.28	0.23	0.43	0.41	1.80
STATUS	PASSED	PASSED	PASSED	PASSED	PASSED	PASSED

Note: The first sample is not used in the calculations

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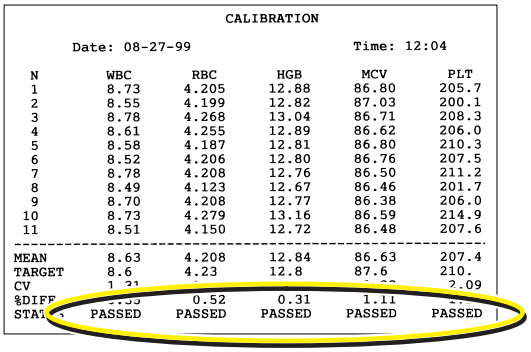
16 Review the status of each result. For information on parameter limits, refer to PERFORMANCE SPECIFICATIONS in the Reference manual.

- If *PASSED* appears for all the parameters, calibration adjustments are not required. Touch the **Return** icon.
  Note: Touching the **Return** icon **does not** update the calibration factors.



CALIBRATION

Date: 08-27-99 Time: 12:04

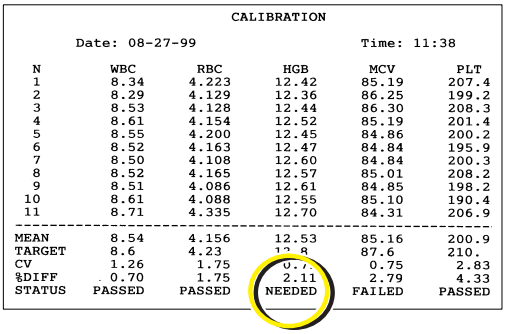
N	WBC	RBC	HGB	MCV	PLT
1	8.73	4.205	12.88	86.80	205.7
2	8.55	4.199	12.82	87.03	200.1
3	8.78	4.268	13.04	86.71	208.3
4	8.61	4.255	12.89	86.62	206.0
5	8.58	4.187	12.81	86.80	210.3
6	8.52	4.206	12.80	86.76	207.5
7	8.78	4.208	12.76	86.50	211.2
8	8.49	4.123	12.67	86.46	201.7
9	8.70	4.208	12.77	86.38	206.0
10	8.73	4.279	13.16	86.59	214.9
11	8.51	4.150	12.72	86.48	207.6
MEAN	8.63	4.208	12.84	86.63	207.4
TARGET	8.6	4.23	12.8	87.6	210.
CV	1.31				2.09
%DIFF	0.35	0.52	0.31	1.11	
STATUS	PASSED	PASSED	PASSED	PASSED	PASSED

- If *NEEDED* appears for any of the parameters, calibration adjustments are required.

  Touch the **Save and Exit** icon to automatically replace the *NEEDED* calibration factor with the new calibration factor. This automatically updates the instrument's calibration parameters.

  Print the new calibration factors and place them in your log book.

  Verify calibration by analyzing one replicate for each level of control.



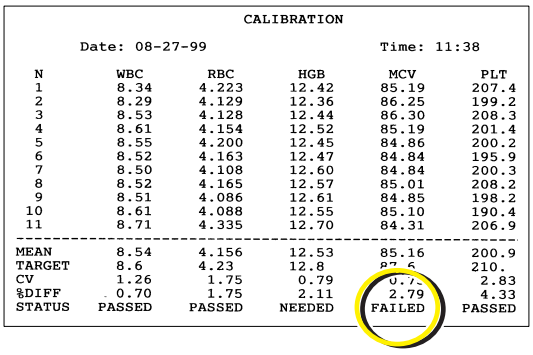
CALIBRATION

Date: 08-27-99 Time: 11:38

N	WBC	RBC	HGB	MCV	PLT
1	8.34	4.223	12.42	85.19	207.4
2	8.29	4.129	12.36	86.25	199.2
3	8.53	4.128	12.44	86.30	208.3
4	8.61	4.154	12.52	85.19	201.4
5	8.55	4.200	12.45	84.86	200.2
6	8.52	4.163	12.47	84.84	195.9
7	8.50	4.108	12.60	84.84	200.3
8	8.52	4.165	12.57	85.01	208.2
9	8.51	4.086	12.61	84.85	198.2
10	8.61	4.088	12.55	85.10	190.4
11	8.71	4.335	12.70	84.31	206.9
MEAN	8.54	4.156	12.53	85.16	200.9
TARGET	8.6	4.23	12.8	87.6	210.
CV	1.26	1.75	0.7	0.75	2.83
%DIFF	0.70	1.75	2.11	2.79	4.33
STATUS	PASSED	PASSED	NEEDED	FAILED	PASSED

- If *FAILED* appears, the % diff value and/or CV% exceeds the high acceptable limit.

  You cannot save *FAILED* calibration results. Call your local Coulter Service Representative for assistance.



CALIBRATION

Date: 08-27-99 Time: 11:38

N	WBC	RBC	HGB	MCV	PLT
1	8.34	4.223	12.42	85.19	207.4
2	8.29	4.129	12.36	86.25	199.2
3	8.53	4.128	12.44	86.30	208.3
4	8.61	4.154	12.52	85.19	201.4
5	8.55	4.200	12.45	84.86	200.2
6	8.52	4.163	12.47	84.84	195.9
7	8.50	4.108	12.60	84.84	200.3
8	8.52	4.165	12.57	85.01	208.2
9	8.51	4.086	12.61	84.85	198.2
10	8.61	4.088	12.55	85.10	190.4
11	8.71	4.335	12.70	84.31	206.9
MEAN	8.54	4.156	12.53	85.16	200.9
TARGET	8.6	4.23	12.8	87.6	210.
CV	1.26	1.75	0.79	0.7	2.83
%DIFF	0.70	1.75	2.11	2.79	4.33
STATUS	PASSED	PASSED	NEEDED	FAILED	PASSED

17 Verify calibration by running 4C PLUS cell control. See Running COULTER 4C® PLUS Cell Control under Heading 2.2, RUNNING CONTROLS for instructions.

6.1 GENERAL MAINTENANCE

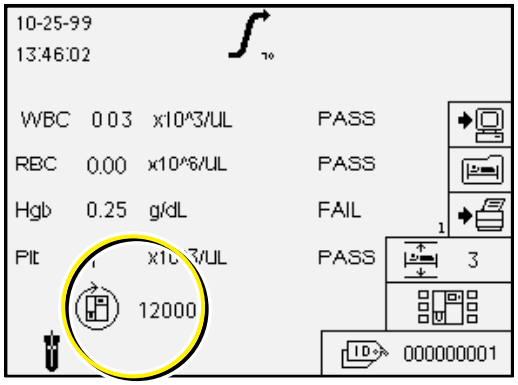
This chapter details the A^{C}•T diff 2 analyzer maintenance procedures that are your responsibility. It also includes a troubleshooting guide to help you solve instrument problems.

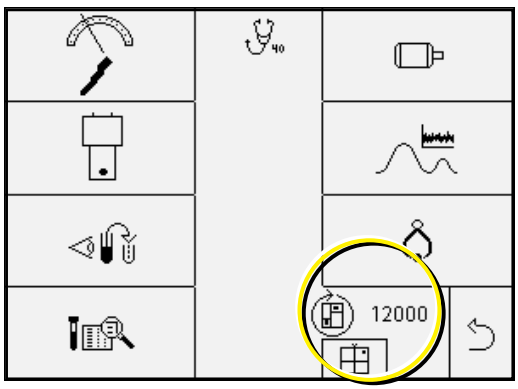
You perform maintenance procedures either on a time schedule or on an instrument cycle schedule. Keep a calendar marked with dates for maintenance and check the Startup results screen for the number of cycles performed.

CAUTION Incorrectly performed maintenance procedures can damage the A^{C}•T diff 2 analyzer. Do not attempt any procedures that are not included in this manual or in the instrument replacement cards. Call your Beckman Coulter Representative for service and maintenance beyond the scope of Coulter documentation.

Cycle Counter

The cycle count appears on the Startup results screen and on the Diagnostics screen. The cycle number prints on the Startup report.



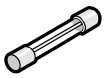


6.2 MAINTENANCE SCHEDULE

Table 6.1 Maintenance Schedule

Maintenance Procedure	Frequency	Situation
Startup	Daily	• Coming out of Shutdown (you touch the **Continue** icon on the screen). • Automatically occurs when powering up after turning the power off during a cycle or after a power interruption during a cycle. • Automatically occurs when powering on more than 2 hours after the previous sample was run.
Shutdown	Daily	You run Shutdown to clean the instrument. If you consistently run less than 5 samples per day, you may perform Shutdown every other day.

Table 6.1 Maintenance Schedule *(Continued)*

Maintenance Procedure	Frequency	Situation
Clean the baths 	When necessary	• Before any type of calibration. • Increased voteouts. • Decreased cell counts. • Increased MCV values. • Increased clog rate (X flag) • Failure to recover control values. • Erratic MCV, RBC and WBC counts.
Calibration 	When necessary or as required by your regulatory agency	• After replacing major component parts such as an aperture bath assembly. • When control values are consistently out of expected assay range.
Replace check valve 	When defective	Clogged or lets liquid or air flow both ways.
Replace fuses 	When blown	• No power. Green power LED is not lit. • Instrument is plugged in but does not run.
Replace probe wipe block 	When defective or plugged.	Fluid drips from probe wipe but vacuum is good and instrument works.
Replace tubing 	Every 3 years	When cracked, leaking or has lost resilience.
Replace vacuum isolator chamber 	When defective	• When you cannot get it clean. • When it is cracked or damaged or creating a vacuum leak. • If there is buildup under the top, causing Plt and WBC noise problems.
Replace Waste filter 	When defective	• Waste does not drain from the baths and VIC • Baths overflow
Replace reagents	When empty	When instrument reports empty and the container is empty.

6.3 CLEANING PROCEDURES

WARNING Risk of biohazard. Utilize appropriate barrier protection when performing these procedures, as the instrument may contain biohazardous material.

These are not routine procedures. Use them only if necessary for troubleshooting or before calibrating.

Zapping the Aperture

Zap the aperture when the instrument:

- Produces increased Aperture Alerts.
- Produces increased voteouts.
- Produces decreased cell counts.
- Produces increased MCV values.
- Fails to recover control values.
- Produces erratic MCV, RBC and WBC counts.

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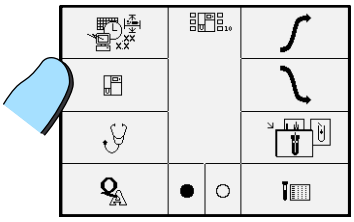
1 At the Main screen, touch the **Diluter Functions** icon.



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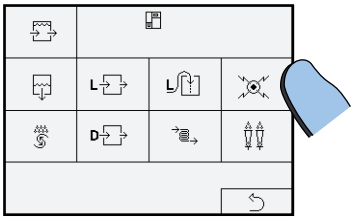
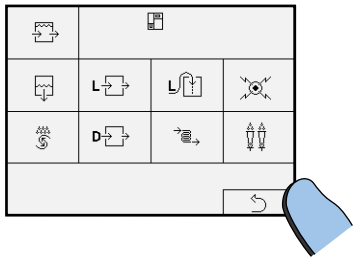
2 At the Diluter Functions screen, touch the **Zap Aperture** icon.



3 At the Diluter Functions screen, touch the **Exit** icon.

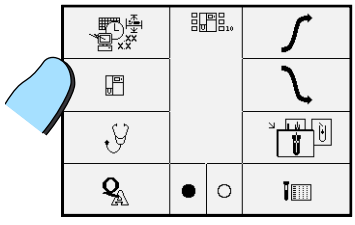


Cleaning (Bleaching) the Baths

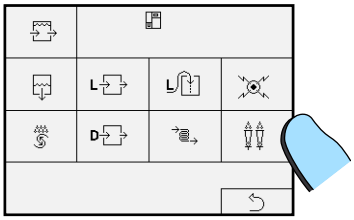
Bleaching removes any clog or debris that restricts proper sample flow. Occasionally, you must do this procedure for troubleshooting.

1 Fill a tube (from which the A^{C}•T diff 2 analyzer can aspirate) with more than 1 mL of high quality, fragrance-free bleach (5% sodium hypochlorite - available chlorine).

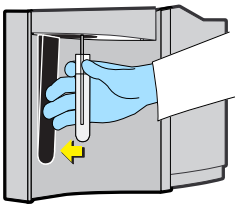
2 At the Main screen, touch the **Diluter Functions** icon.



3 At the Diluter Functions screen, touch the **Clean Baths** icon.



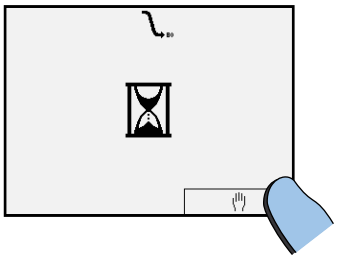
4 Present the tube to the probe so that the tip is well into the bleach, and press the aspirate switch.



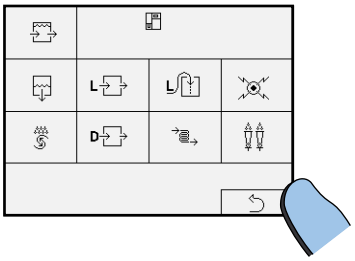
5 The instrument cleans the baths.

6 The cleaning procedure takes approximately 15 minutes to be completed.

Note: If you want to cancel the cleaning procedure before the 15 minute cleaning period ends, touch the **Stop** icon.



When the procedure is completed, the Diluter Functions screen reappears. Touch the **Exit** icon to exit the screen.



Cleaning the Outside of the Instrument

Clean the outside of the instrument with a damp cloth and distilled water. This prevents the buildup of corrosive deposits. Clean up spills promptly. Pay particular attention to the probe wipe housing.

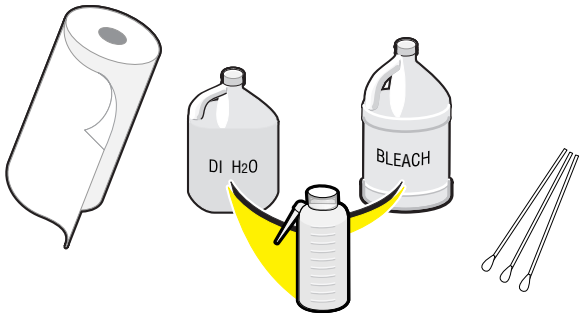
Cleaning the Inside of the Instrument

Clean the inside of the instrument (behind the front door and beneath the bath shield) with a damp cloth and distilled water if obvious evidence of corrosive deposits exists. Be careful not to wipe contaminants into the bath.

Cleaning the Closed Vial Station

If you have a spill or excessive buildup in the Closed Vial Station, do the following procedure immediately.

Tools/Supplies Needed



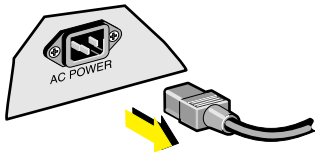
- ❑ Paper towels
- ❑ Bleach solution (9 parts distilled water, 1 part high quality, fragrance-free bleach (5% sodium hypochlorite - available chlorine)
- ❑ Cotton swabs

---

1 Turn off the instrument.

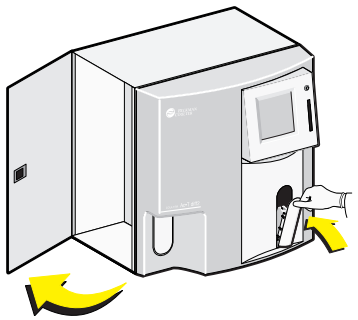
---

2 Unplug the instrument from its power source.

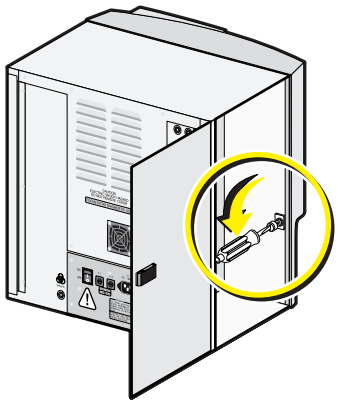


CAUTION Risk of instrument damage. If the instrument's front door is opened when the Cap Pierce door is open, the instrument may be damaged. Before opening the instrument's front door, verify that the Cap Pierce door is closed.

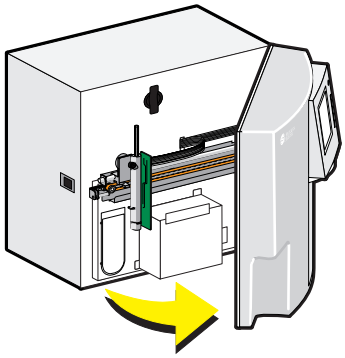
3 Open the left door.



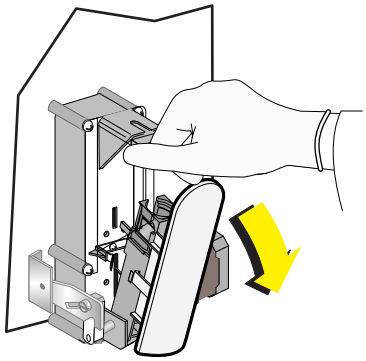
4 Use a regular (flat) screwdriver to turn the fastener that secures the front door.



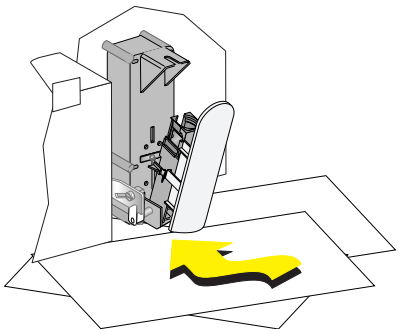
5 Pull the front door open.



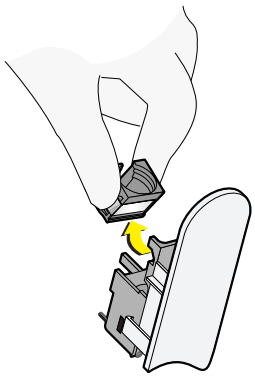
6 Open the tube holder door so that the tube holder is visible.



7 Place paper towels beneath the Cap Pierce Module.

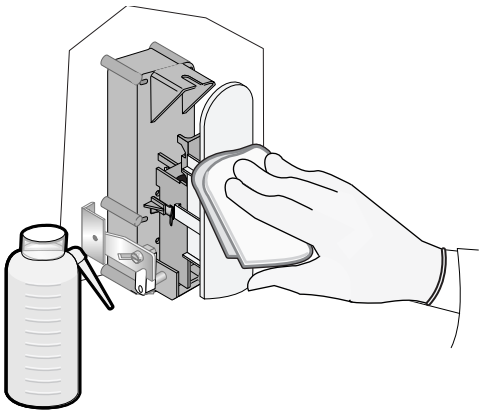


8 Remove the tube holder by pinching the clips together and sliding the holder out of its slot.

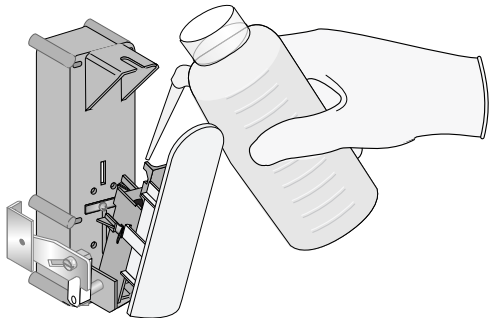


9 Verify that the Cap Pierce Door is free of debris. If necessary, do the Cleaning the Closed Vial Door procedure

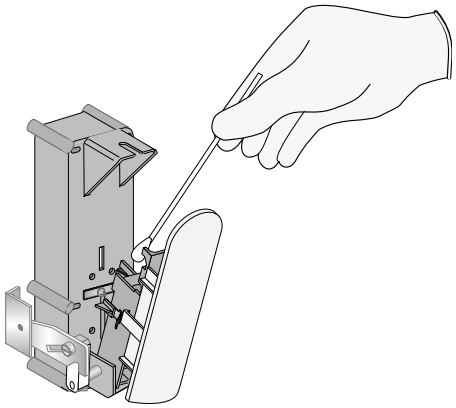
10 Wipe off the Cap Pierce Door with the diluted bleach solution.



11 Squirt bleach solution into the tube detector area.

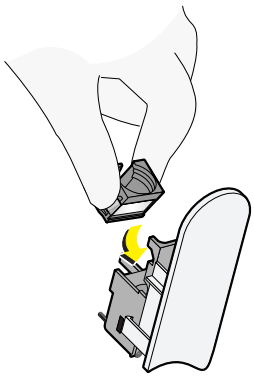


12 Using a cotton swab, wipe off the inside of the tube detector area.

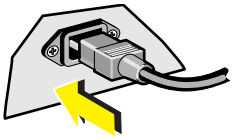


13 Properly dispose of all cleaning material.

14 Replace the tube holder that you removed in step 8. Be sure to position the opening towards the back of the instrument and to snap the holder into place.



15 Plug instrument into power source.

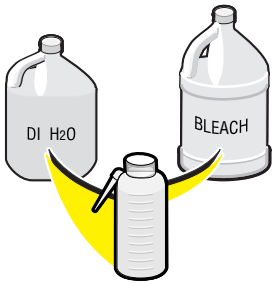


16 Turn instrument on, and resume normal operation.

Cleaning the Closed Vial Door

Tools/Supplies Needed

- ❑ Bleach solution: 9 parts distilled water, 1 part high quality, fragrance-free bleach (5% sodium hypochlorite - available chlorine)

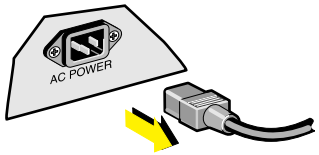


---

1 Turn off the instrument.

---

2 Unplug the instrument from its power source.



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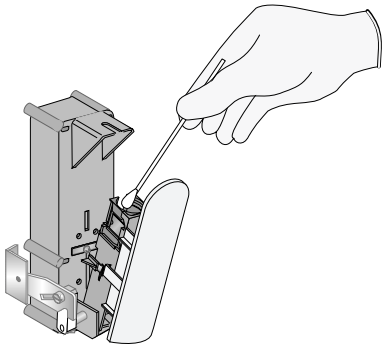
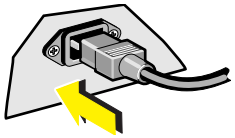
3 Using a cotton swab, clean the inside of the tube holder.



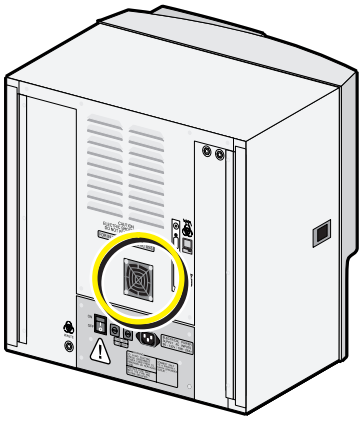
4 Plug the instrument into its power source.



5 Turn the instrument on and resume normal operation.

Cleaning the Fan's Dust Filter

The fan is located on the back panel, and the filter is inside the fan's housing.



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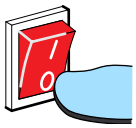
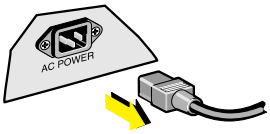
1 Turn off the instrument.



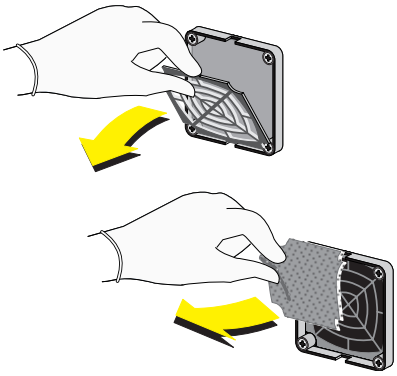
---

2 Unplug the instrument from its power source.



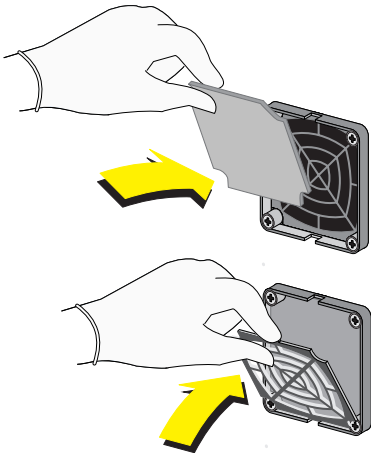
---

3 Remove the grill and filter.

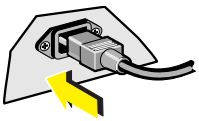


4 Clean the filter in water, and dry thoroughly.

5 Replace the filter and grill.



6 Plug the instrument into its power source.



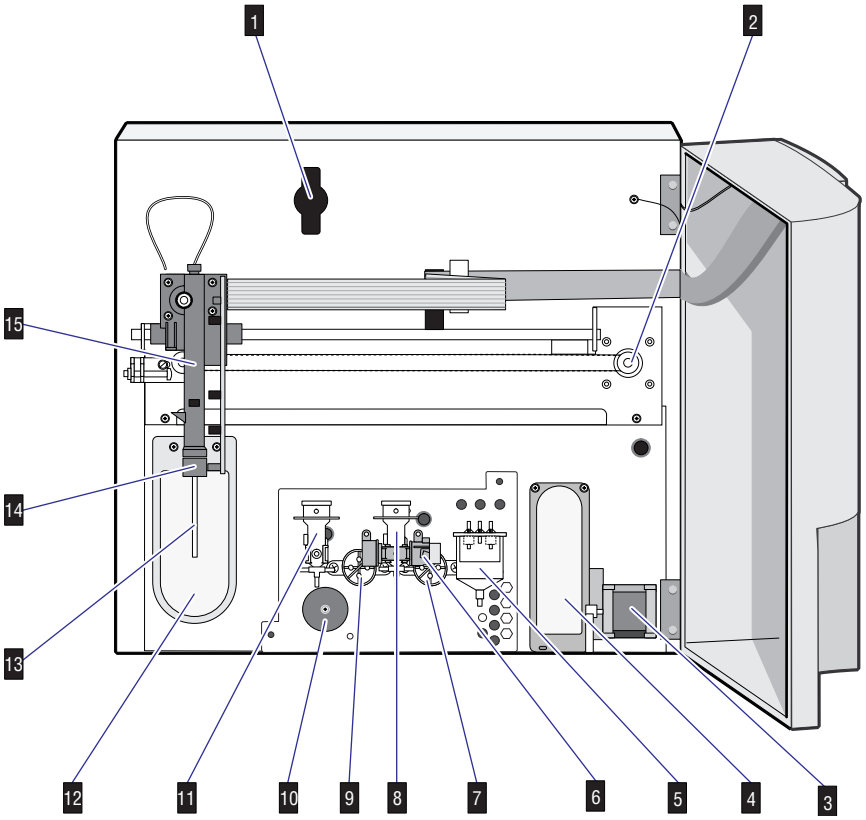
7 Turn the instrument on and resume normal operation.

6.4 CALIBRATION PROCEDURES

See Chapter 5, Calibration.

6.5 A^C•T diff 2 ANALYZER COMPONENT LOCATIONS

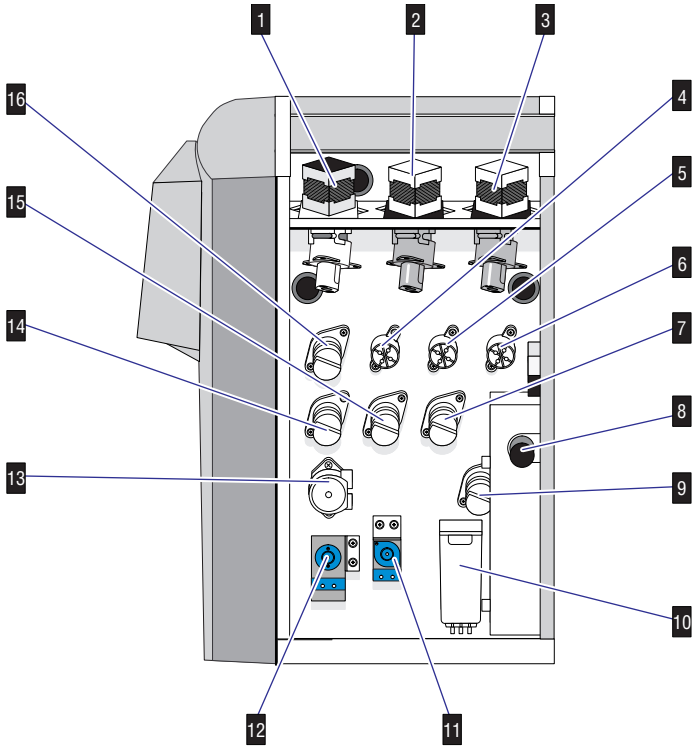
Inside Front



1 Software Card Slot
2 Horizontal Traverse Motor
3 Closed Vial Sample Handler Motor
4 Closed Vial Sample Handler
5 Vacuum Isolator Chamber
6 Hgb Lamp
7 LV17†
8 WBC Bath
9 LV16‡
10 Sweepflow Spool
11 RBC Bath
12 Aspirate Switch: Open Vial and Predilute
13 Probe
14 Probe Wipe Block
15 Horizontal Traverse Assembly

†LV17 On = Opens/Off = Closes count path from WBC bath
‡LV16 On = Opens/Off = Closes count path from RBC bath

Inside Right



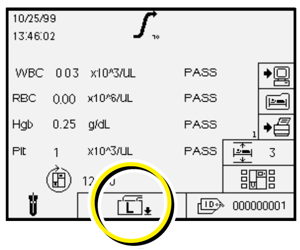
1. Sample Pump (50 µL)
2. Diluent Pump (100 µL)
3. Lyse Pump (100 µL)
4. LV9 (Diluent reservoir fill enable)
5. LV10 (Probe wash diluent select)
6. LV11 (WBC/RBC bath diluent select)
7. LV12 (WBC bath drain enable)
8. Vacuum Adjust Knob
9. LV18 (Waste/Rinse select)
10. Diluent Reservoir
11. Diluent Reservoir Pump
12. Waste/Rinse Pump
13. Rinse Pump
14. LV7 (VIC drain enable)
15. LV15 (RBC bath drain enable)
16. LV8 (Probe wipe waste enable)

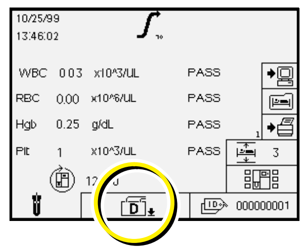
6.6 REPLACEMENT PROCEDURES

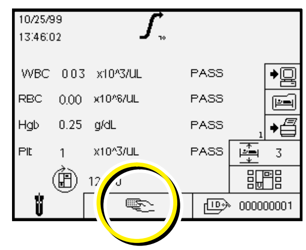
Replacing Reagents

For information on connecting the reagents the first time, see the Installation and Training Guide.

A change of reagents may be necessary when you see one of these symbols:







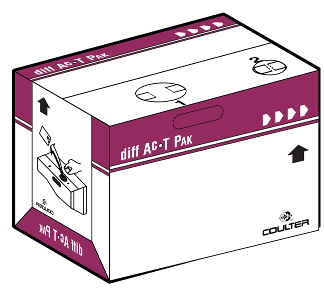
Replacing the diff A^{C}•T Pak Reagent

Periodically check the expiration date on the reagent container. Do not use an expired reagent. Replace the reagent if the existing reagent is expired or empty.

---

1 Be sure your reagent is the diff A^{C}•T Pak reagent.

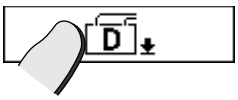
Note: If you have the diff A^{C}•T Tainer reagent, do the Replacing the diff A^{C}•T Tainer Reagent procedure.



2 Check to see if the reagent container is empty.

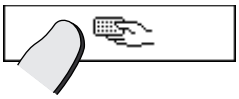
- If the container is not empty, touch one of the **Reagent** icons or the **Reagent Management Card** icon on the screen to prime.

  If the container is not empty but the **Reagent Management Card** icon continues to appear, reinsert the reagent card. If the problem persists, go to step 3.
- If the container is empty, go to step 3.



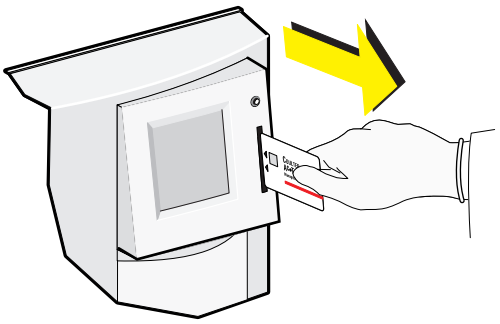
or

or

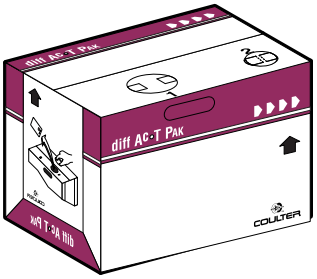


3 Remove the diff A^{C}•T Pak reagent management card from the instrument.

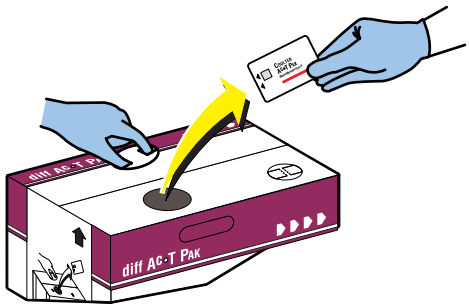
Note: Keep the card for use with IQAP if your laboratory is a participant in Coulter's IQAP program.



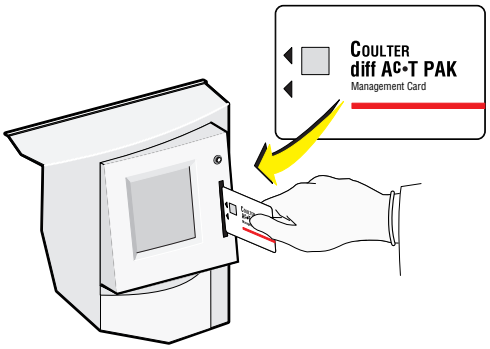
4 Get a new diff A^{C}•T Pak reagent container.



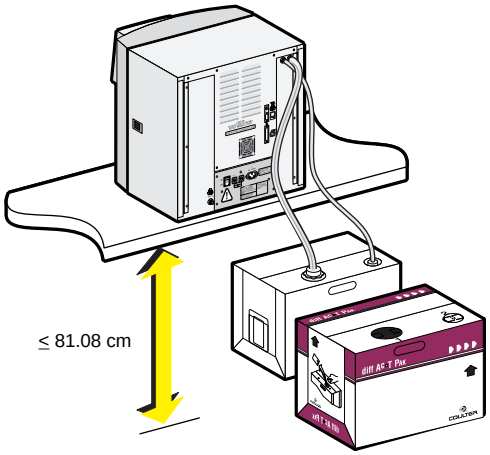
5 Pull the perforated cardboard from the reagent container box, and remove the management card.



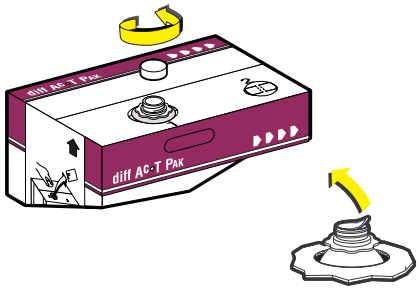
6 At the front of the instrument, insert the management card from the reagent container into the slot, with the contact area facing the touch screen.



7 Place the new reagent container on the floor next to the empty container.

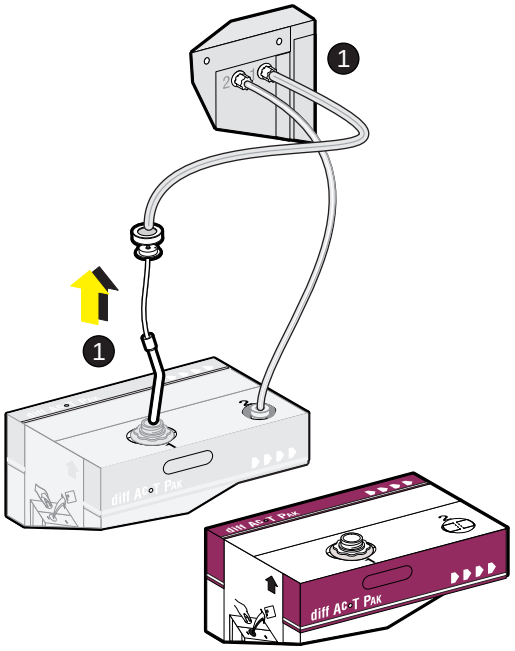


8 Remove the cap and seal for tube number 1.

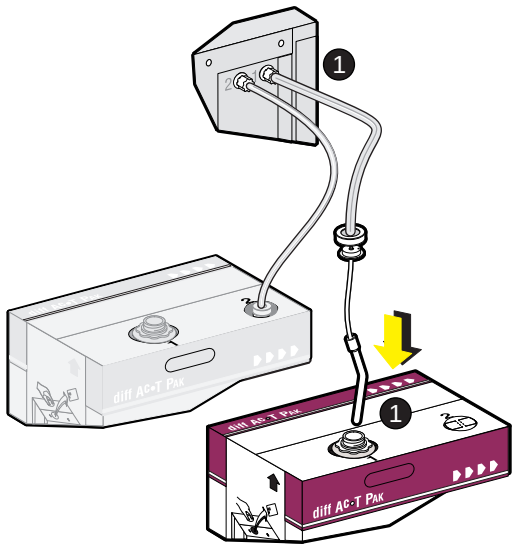


IMPORTANT Risk of misleading results if the pickup tubes are contaminated. Ensure that the reagent pickup tubes remain clean and free of contamination.

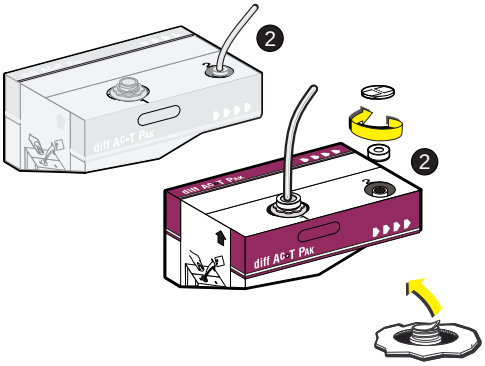
9 Remove reagent pickup tube 1 from the empty reagent container.



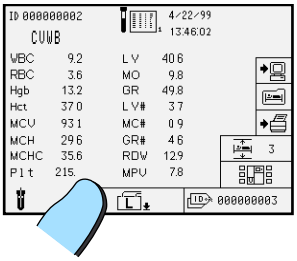
10 Insert reagent pickup tube 1 into the new container and tighten the cap.



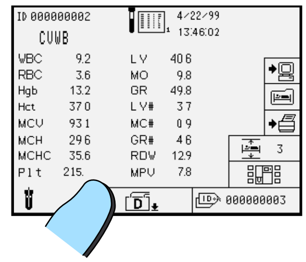
11 Repeat steps 9 and 10 for reagent pickup tube 2.



12 Touch the **Lyse Prime** icon, if displayed.



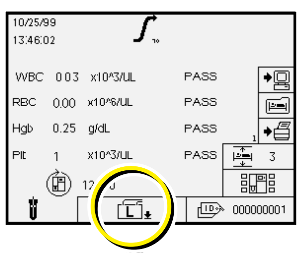
13 Touch the **Diluent Prime** icon, if displayed.

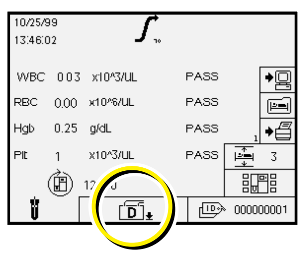


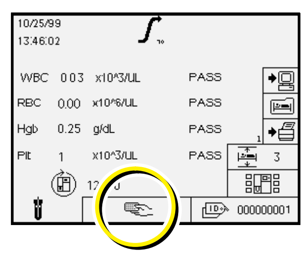
14 In your laboratory log book, record the reagent lot number and expiration date from the new diff A^{C}•T Pak reagent.

Replacing the diff A^{C}•T Tainer Reagent

Change the reagent container when you see one of these symbols

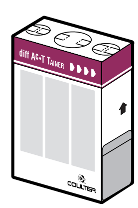






1 Be sure your reagent is the diff A^{C}•T Tainer reagent.

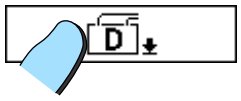
If you have the diff A^{C}•T Pak reagent, do the Replacing the diff A^{C}•T Pak Reagent procedure.



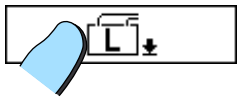
2 Check to see if the reagent container is empty.

- If the container is not empty, touch the **Reagent** icon or the **Reagent Management Card** icon on the screen to prime.

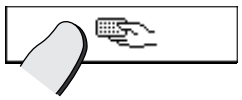
  If the container is not empty but the **Reagent Management Card** icon continues to appear, reinsert the reagent card. If the problem persists, go to step 3.
- If the container is empty, go to step 3.



or

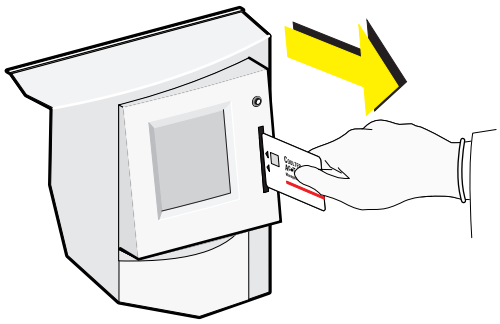


or

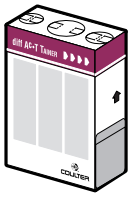


3 Remove the diff A^{C}•T Tainer reagent management card from the instrument.

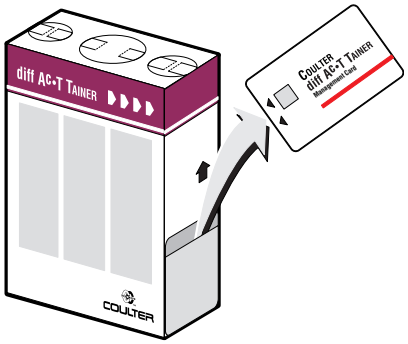
Note: Keep the card for use with IQAP if your laboratory is a participant in Coulter's IQAP program.



4 Get a new diff A^{C}•T Tainer reagent container.

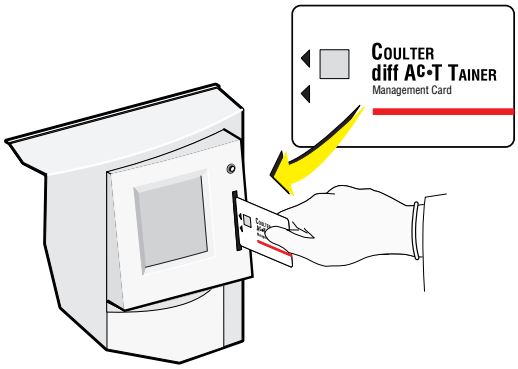


5 Remove the new reagent management card from the sleeve on the reagent container.

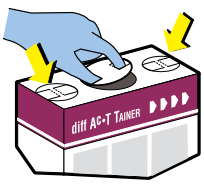


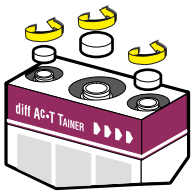
6 Insert the diff A^{C}•T Tainer reagent management card from the new reagent container into the slot at the front of the instrument.

Be sure the contact area is facing the touch screen.



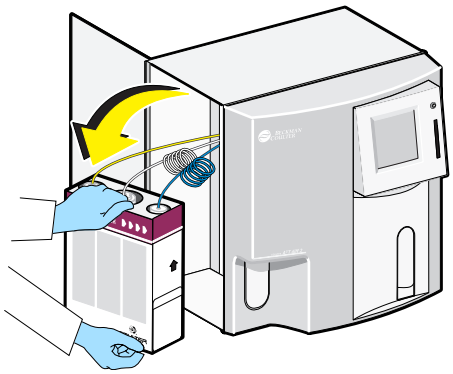
7 Unscrew the three white plastic caps from the container.





8 Remove the seals to expose each opening.

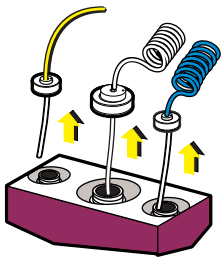
9 Open the reagent compartment door and remove the empty diff A^{C}•T Tainer reagent.



10 Remove the pickup tubes from the reagent container:

a. Unscrew the caps.

b. Pull the reagent tubes from the container.



IMPORTANT Risk of misleading results if the pickup tubes are contaminated. Ensure that the reagent pickup tubes remain clean and free of contamination.

11 Connect pickup tubes 1, 2, and 3 to the new reagent container box:

a. Insert the cap end of pickup tube 1 into opening 1 of the reagent container.

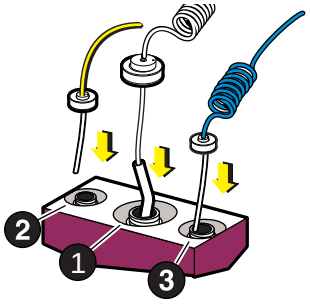
b. Screw the cap to the container.

c. Insert the cap end of pickup tube 2 into opening 2 of the reagent container.

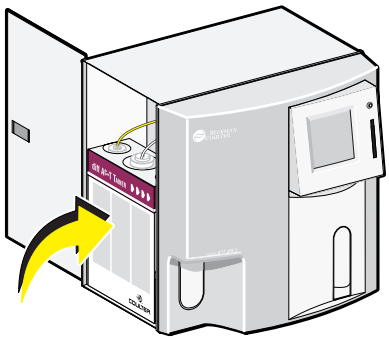
d. Screw the cap to the container.

e. Insert the cap end of pickup tube 3 into opening 3 of the reagent container.

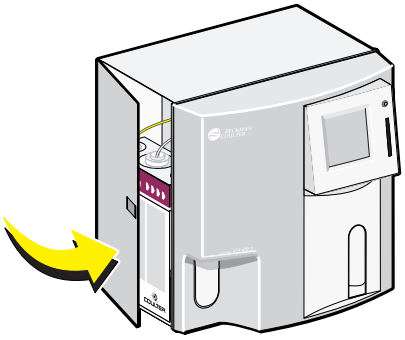
f. Screw the cap to the container.



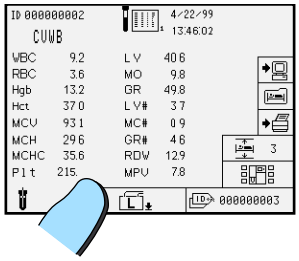
12 Place the container, with tubes attached, in the reagent compartment.



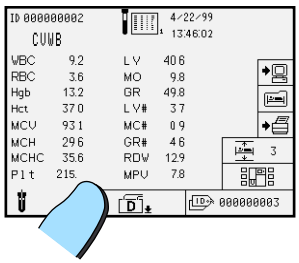
13 Close the reagent compartment door.



14 Touch the **Lyse Prime** icon, if displayed.



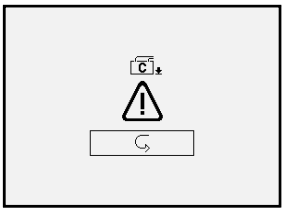
15 Touch the **Diluent Prime** icon, if displayed.



16 In your laboratory log book, record the reagent lot number and expiration date from the new diff A^{C}•T Tainer reagent.

Replacing the A^{C} •T Rinse Shutdown Diluent

Replace the diluent when you see this screen:



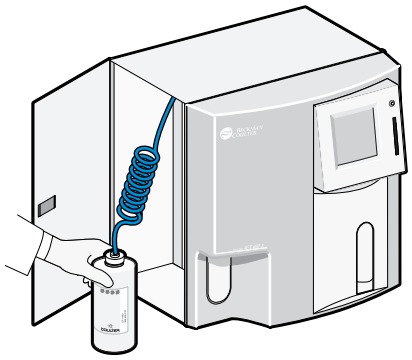
---

1 Check to see if the A^{C}•T Rinse shutdown diluent container is empty.

- If it is not empty, touch the **Continue** icon to prime the rinse lines.
- If it is empty, go to step 2.

---

2 Open the reagent compartment door and remove the rinse container (with tubing still attached.)

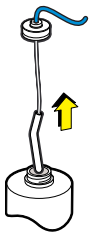


---

3 Remove pickup tube from the rinse container:

a. Unscrew the cap.

b. Pull the tube from the container.

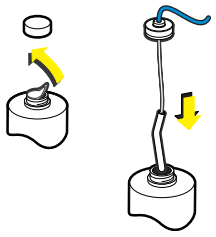


IMPORTANT Risk of misleading results if the pickup tubes are contaminated. Ensure that the reagent pickup tubes remain clean and free of contamination.

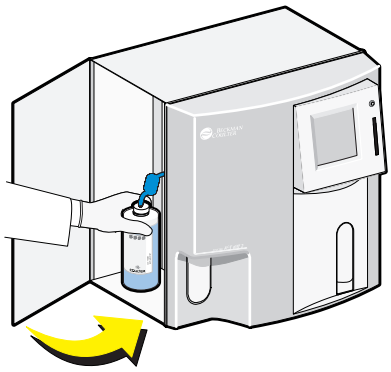
4 Connect pickup tubes to the new diluent container:

a. Insert the cap end of pickup tube into the rinse container.

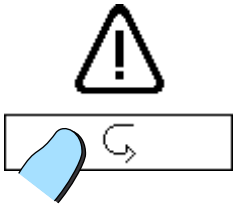
b. Screw the cap to the box.



5 Place the new rinse container into the reagent management compartment and close the door.

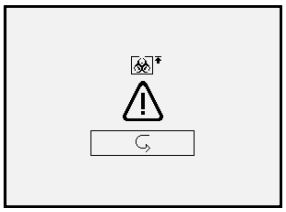


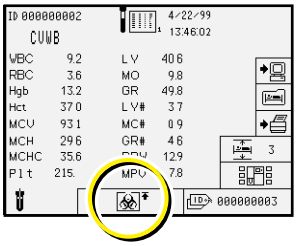
6 Touch the **Continue** icon.



Replacing the Waste Container

Replace the waste container when you see either of these screens:

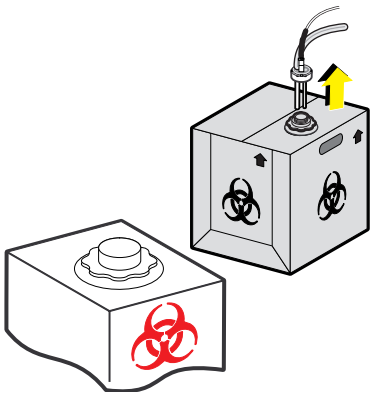




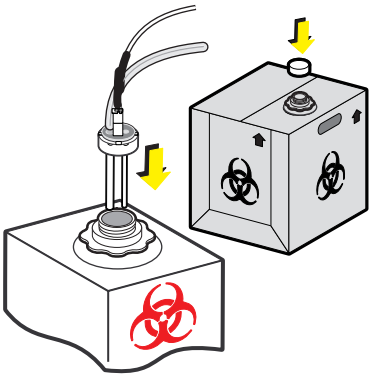
WARNING Risk of biohazard. Waste can include biohazardous material that could cause contamination. Handle and dispose of according to acceptable laboratory standards.

Risk of biohazard if instrument is operated when the waste level sensor is disconnected. Prevent the biohazard by operating the instrument when the waste level sensor is connected.

1 Remove the tubing from the full waste container.

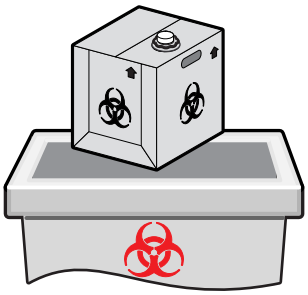


2 Insert the tubing into the new waste container, securing the cap by turning clockwise.



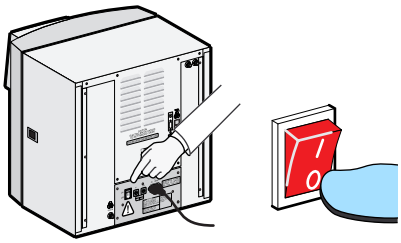
3 Touch the **Continue** icon.

4 Place a cap on the full waste container and dispose of properly.

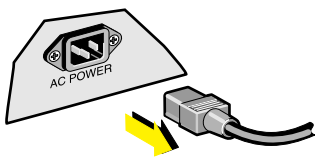


Replacing the Vacuum Fluid Barrier

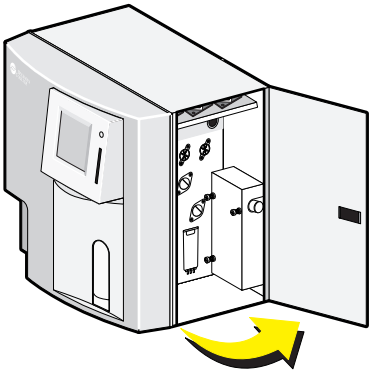
1 Turn the instrument off.



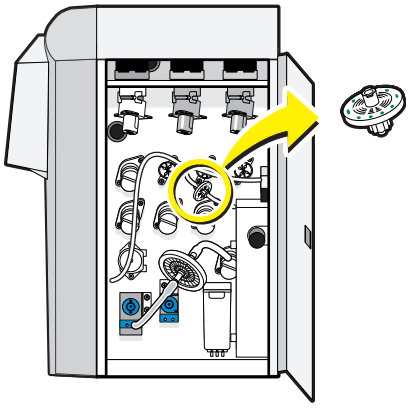
2 Unplug the instrument from its power source.



3 Open the right compartment door.

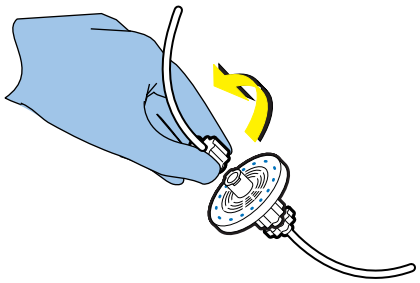


4 Locate the vacuum fluid barrier.

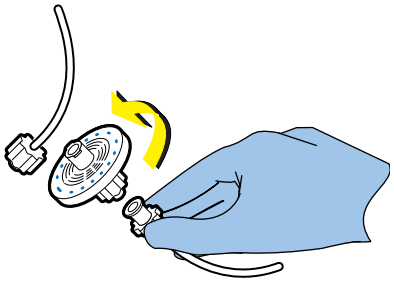


5 Remove the vacuum fluid barrier from the tubing:

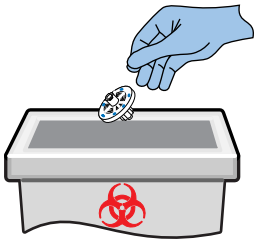
a. Twist off the top connector.



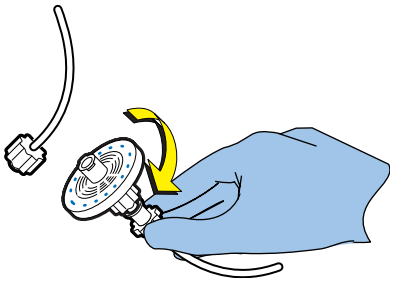
b. Twist the fluid barrier off the bottom connector.



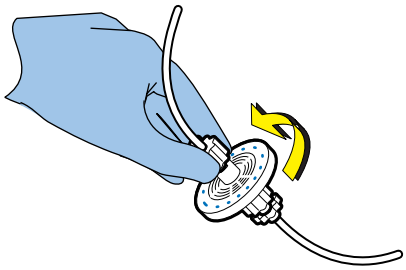
6 Properly dispose of used fluid barrier.



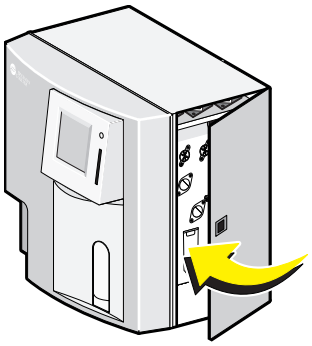
7 Connect a new fluid barrier to the tubing by inserting tubing end into filter and turning the connector until secure.



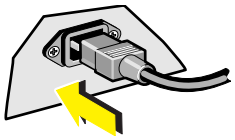
8 Repeat step 7 to connect the other end of the fluid barrier.



9 Close the right door.



10 Plug the instrument into its power source.



11 Turn the instrument on and resume normal operation.

12 Cycle a sample with known results to verify instrument performance.

Note: If a vacuum error appears, adjust the vacuum. See the Adjusting the Vacuum procedure.

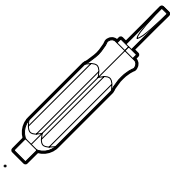
Replacing Check Valves

Check valves allow liquid or air to flow through in one direction only.

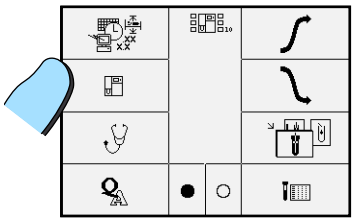
Replace a check valve if:

- It is clogged.
- It lets liquid or air flow both ways.

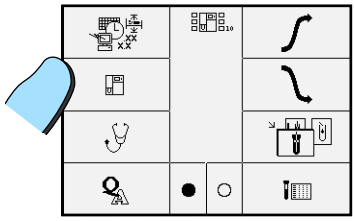
A regular, flathead screwdriver is needed for this procedure.

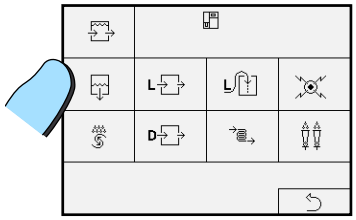


1 At the main menu screen, touch the **Diluter Functions** icon.



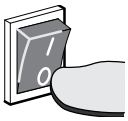
2 If you are replacing a check valve connected to the bottom of the counting baths, touch the **Drain Baths** icon at the Diluter Functions screen.





If you are replacing a check valve **not** connected to the counting baths, go to step 3.

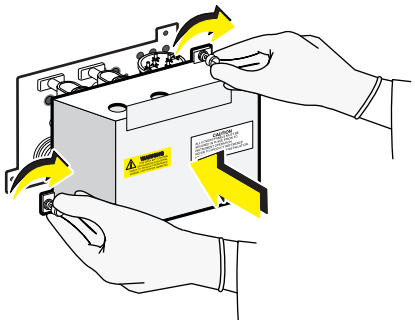
3 Turn the instrument off.



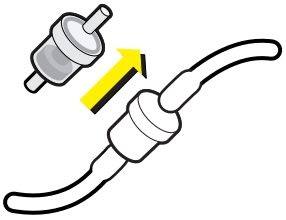
If you are replacing a check valve not connected to the counting baths, go to step 6.

4 Open the appropriate compartment door.

5 Remove the bath shield/cover.



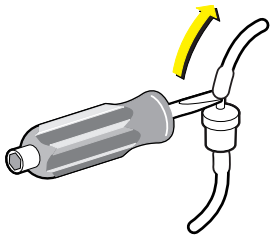
CAUTION Risk of instrument damage and/or misleading results if the check valve is inserted in the wrong orientation. Be sure to orient (point) the new check valve in the same direction as the old one.



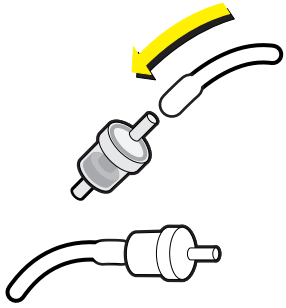
6 Note the direction that the check valve is pointing before you remove it.

WARNING Biohazardous material might be contained in the check valves and associated tubing and could cause contamination unless handled with care. Wear protective gear. Avoid skin contact. Clean up spills immediately. Dispose of valve and tubing according to acceptable laboratory procedures for biohazardous materials.

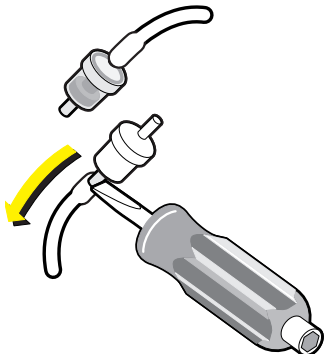
7 Use a screwdriver to pry the tubing from the top of the check valve.



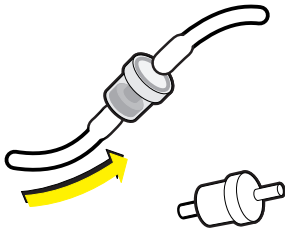
8 Connect the tubing to the top of the new check valve.



9 Use a screwdriver to pry the tubing from the bottom of the old check valve.



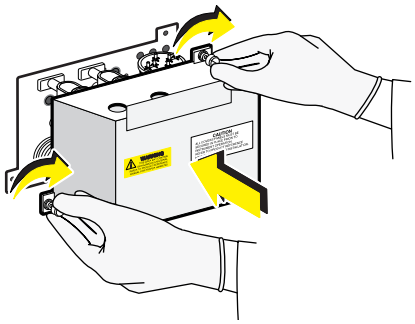
10 Connect the tubing to the bottom of the new check valve. Be sure you properly orient the replacement valve.



11 Properly dispose of used check valve.

12 If you replaced a check valve that was connected to one of the counting baths in the front of the instrument, replace the metal cover.

If you did not replace a check valve that was connected to one of the counting baths, go to step 13.



13 Turn the instrument on and resume normal operation.

14 Cycle a sample with known results to verify instrument performance.

Watch the sample and ensure that the check valve is working properly and does not leak.

15 After you verify that the check valve is not leaking, close all instrument doors and resume normal operation.

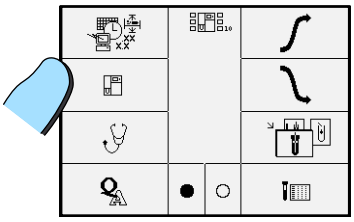
Replacing Tubing

Replace tubing if it is cracked, leaking or has lost resilience.

Scissors are needed for this procedure.

---

1 At the main menu screen, touch the **Diluter Functions** icon.



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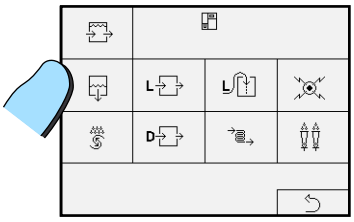
2 At the Diluter Functions screen, touch the **Drain Baths** icon.



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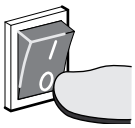
3 Turn the instrument off.



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4 Remove the tubing section from the two components it connects.

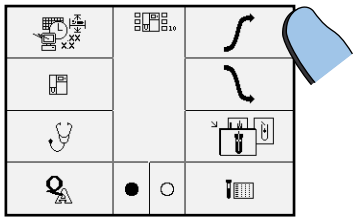
5 Measure the new tubing of the same material, color code and bore size of the old tubing you just removed.

6 Cut the new tubing with scissors at the desired length.

7 Push new tubing onto the two components it is to connect.

8 Turn the instrument on and resume normal operation.

9 At the Main screen, touch the **Startup** icon.



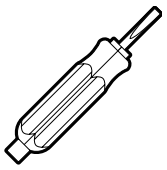
10 Run a sample with known results to verify instrument performance.

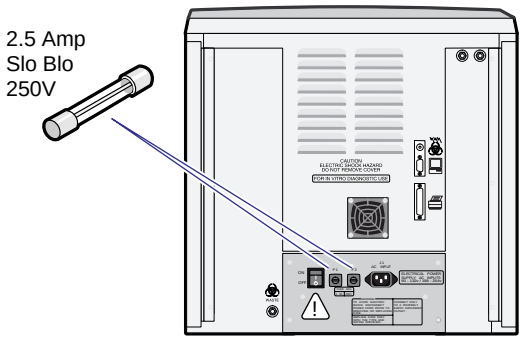
Note: Make sure that the new tubing is correctly connected and does not leak.

Replacing Fuses

Replace fuses as needed.

A regular, flathead screwdriver is needed for this procedure.





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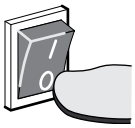
1 Turn the instrument off.



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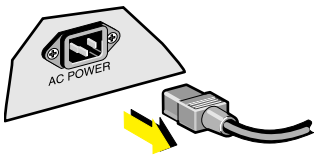
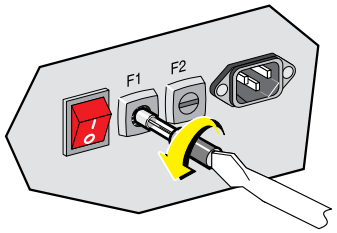
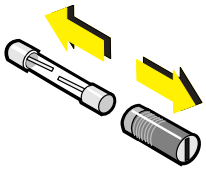
2 Unplug the instrument from its power source.



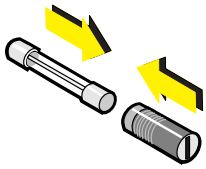
3 Unscrew the fuse holder from the back of the instrument, where F1 is marked.



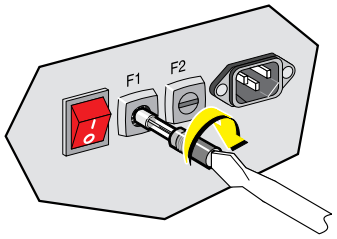
4 Remove the fuse from the holder.



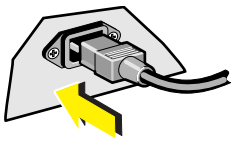
5 Insert the new fuse into the holder.



6 Screw the fuse holder back into the instrument at F1.



7 Plug the power cord back into the instrument at AC INPUT.

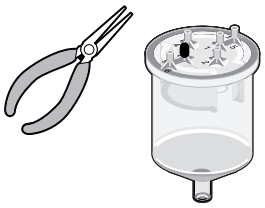


8 Turn the instrument on and resume normal operation.

Replacing the Vacuum Isolator Chamber (VIC)

Replace the Vacuum Isolator Chamber (VIC) when it is defective. See Table 6.1 for defective situations.

Needle-nose pliers are needed for this procedure.



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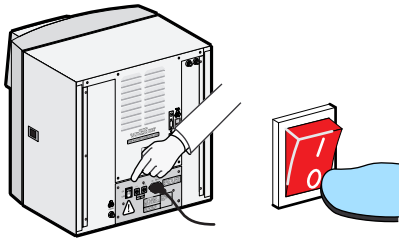
1 Turn the instrument off.



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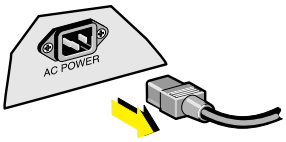
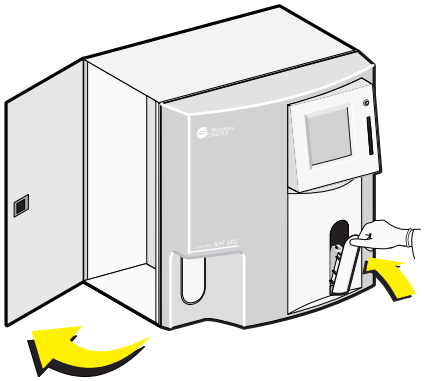
2 Unplug the instrument from its power source.



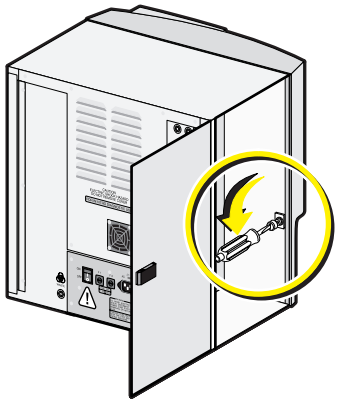
CAUTION Risk of instrument damage. If the instrument's front door is opened when the Cap Pierce door is open, the instrument may be damaged. Before opening the instrument's front door, verify that the Cap Pierce door is closed.

3 Open the front door of the instrument:

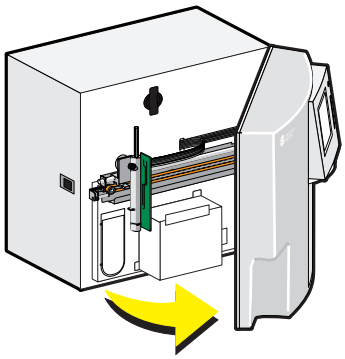
a. Open the left side door.



b. Use a regular (flat) screwdriver to loosen the screw that secures the front door.

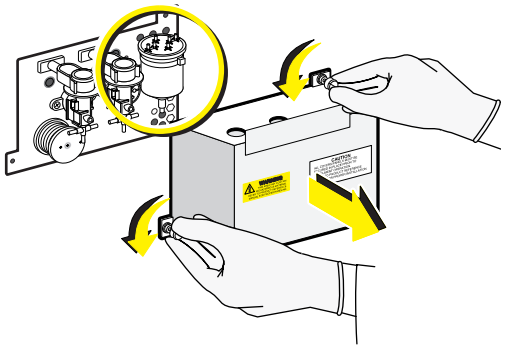


c. Pull open the front door.



WARNING The waste pump tubing can contain biohazardous material that could cause contamination if not handled properly. Handle these components according to acceptable laboratory practices.

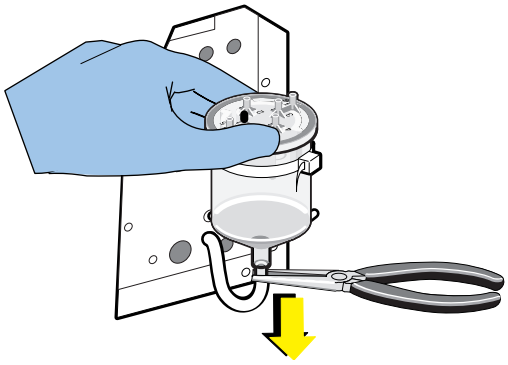
4 Remove the metal cover and locate the VIC.



5 Remove the numbered tubing from the top of the VIC.

Note: If any tubing to the VIC is worn or cracked, replace it with new tubing from your accessory kit. See the Replacing Tubing procedure for instructions.

6 Remove the tubing from the bottom of the VIC.

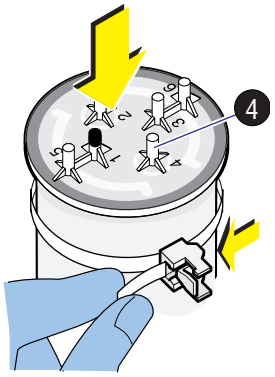


7 Slide the VIC up out of the tie wrap.

Note: If necessary, you can open the tie wrap or cut and replace it.

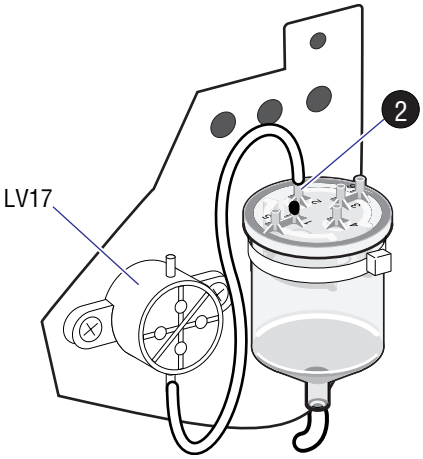
8 Properly dispose of the used VIC.

9 Insert the new VIC into the tie wrap with port 4 facing the front of the instrument. (Tighten the tie wrap if necessary.)



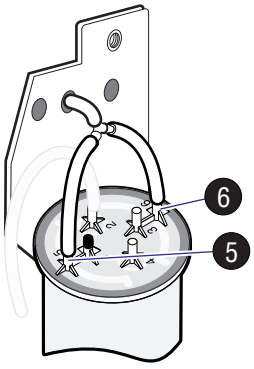
10 Connect the tubing to the bottom of the new VIC.

11 Connect tubing LV17 to fitting number 2 on the VIC, feeding the tubing as shown.

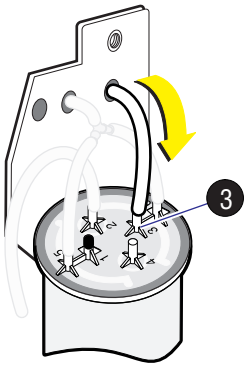


12 Connect the tubing from "Y" fitting number 5 and number 6 on the VIC.

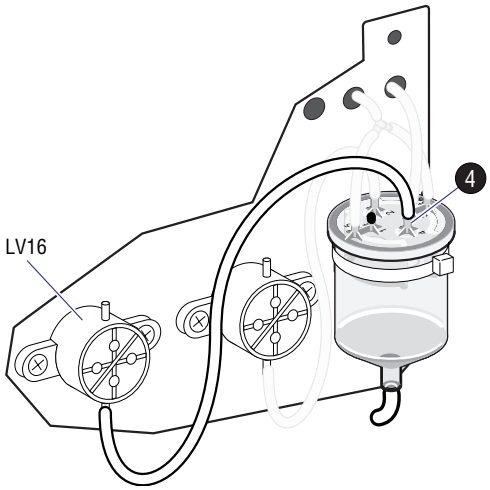
Note: The tubing and the VIC fittings are not numbered the same due to the quantity of fittings throughout the entire instrument.



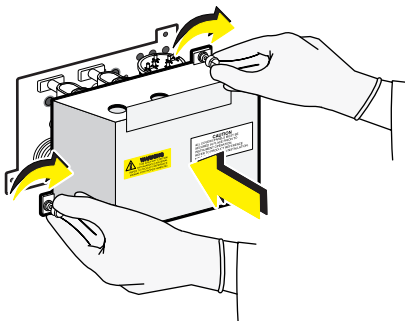
13 Connect tubing to fitting number 3 on the VIC.



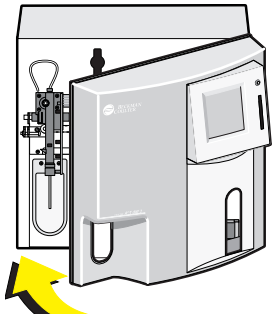
14 Connect tubing from LV16 to fitting number 4 on the VIC.



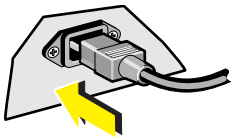
15 Replace the metal cover and secure.



16 Close the front door.



17 Plug the instrument into its power source.

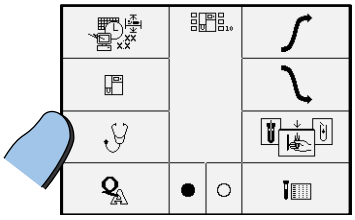


18 Turn the instrument on and resume normal operation.

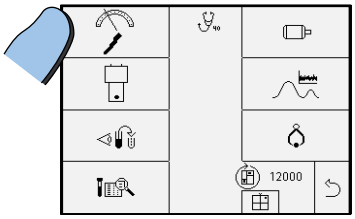
19 Do the Adjusting the Vacuum procedure.

Adjusting the Vacuum

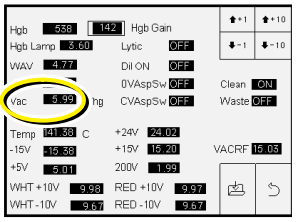
1 At the Main screen, touch the **Diagnostics** icon.



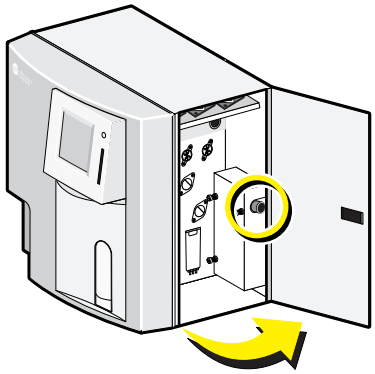
2 At the Diagnostics screen, touch the **Voltages/Sensors** icon.



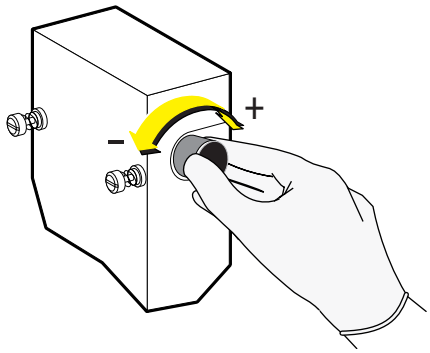
3 Locate the vacuum setting indicator.

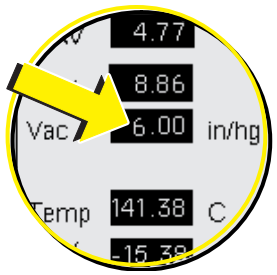


4 Open the right door and locate the vacuum adjustment knob.



5 Turn the knob to adjust the setting to 6.00 in/hg.



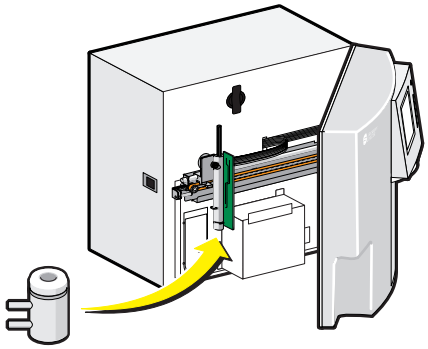


6 Cycle a sample with known results to verify instrument's performance.

Replacing the Probe Wipe

Replace the probe wipe when it is defective or plugged. If fluid drips from the probe wipe but vacuum is good and the instrument works, then the probe wipe is probably defective and you should replace it.

Do not attempt to run the instrument if the probe is bent or loose.



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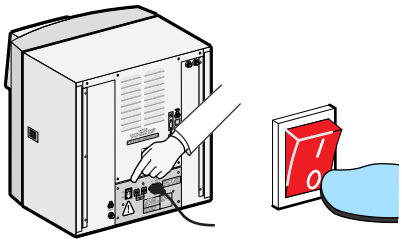
1 Turn the instrument off.



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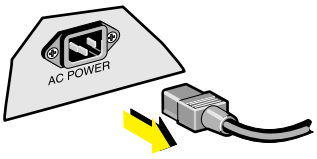
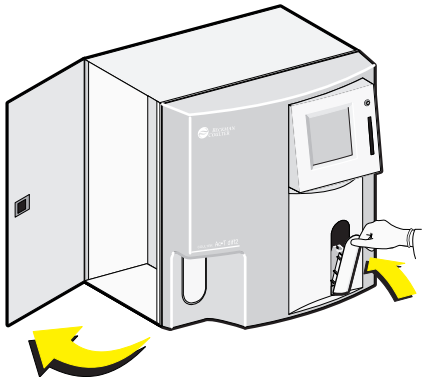
2 Unplug the instrument from its power source.

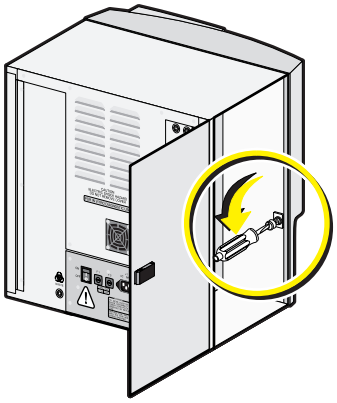


CAUTION Risk of instrument damage. If the instrument's front door is opened when the Cap Pierce door is open, the instrument may be damaged. Before opening the instrument's front door, verify that the Cap Pierce door is closed.

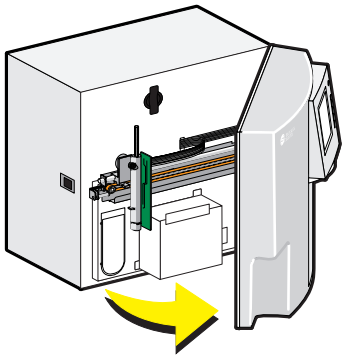
3 Open the left side door.



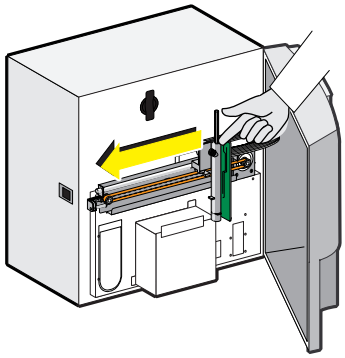
4 Use a regular (flat) screwdriver to turn the fastener that secures the front door.



5 Pull the front door open.

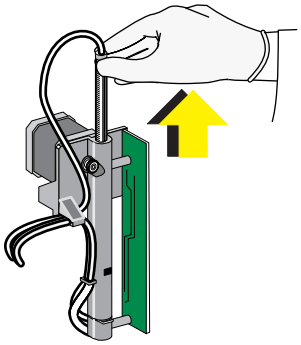


6 Slide the probe assembly to the left.

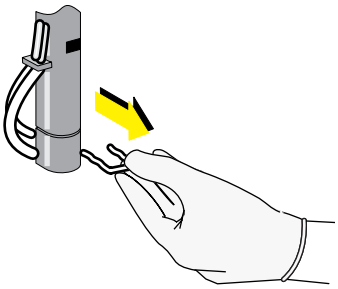


WARNING To avoid being exposed to biohazardous material, adhere to standard laboratory safety procedures.

7 Pull the aspiration probe up into the probe assembly.



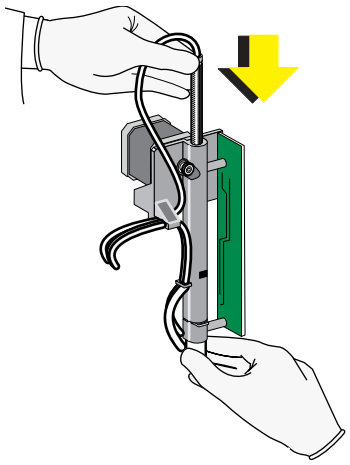
8 Remove the metal clip that holds the probe wipe in the probe assembly.



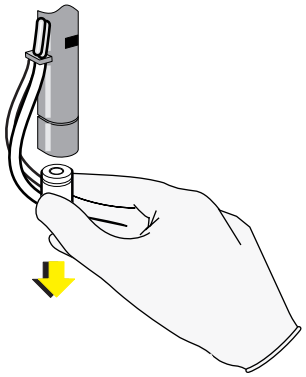
9 Remove the probe wipe from the assembly:

a. Using your left hand, grasp the vertical bar.

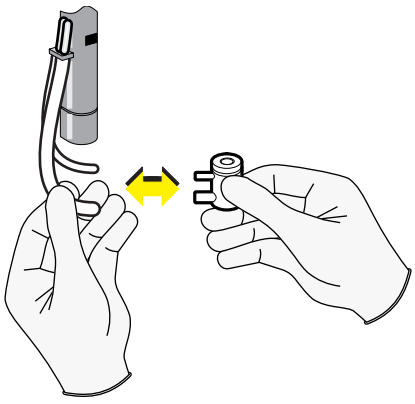
b. Push the probe down to dislodge the probe wipe.



c. Remove the probe wipe from the housing.



10 Disconnect the tubing from the probe wipe.

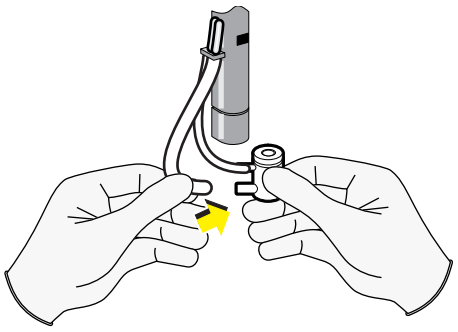


11 Properly dispose of the probe wipe.

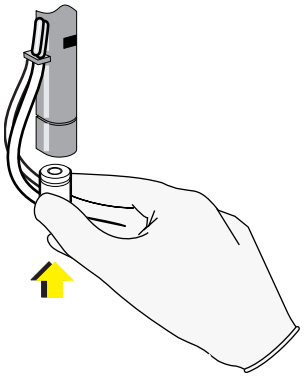
12 Connect the tubing to the new probe wipe:

a. Connect the narrow tubing, number 4, to the top fitting.

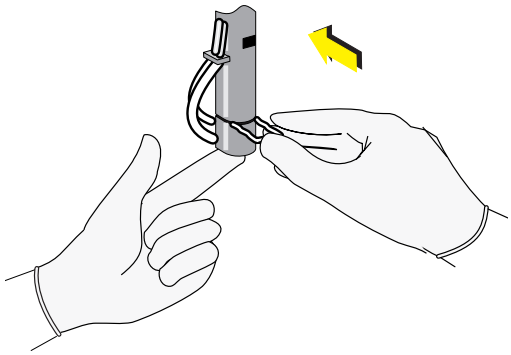
b. Connect the wide tubing, number 5, to the bottom fitting.



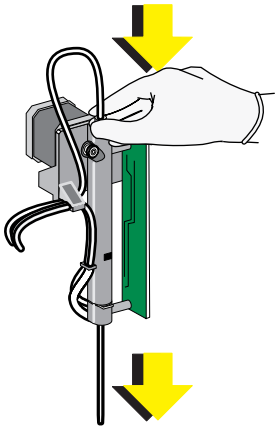
13 Insert the probe wipe into the assembly, with the groove at the top of the wipe.



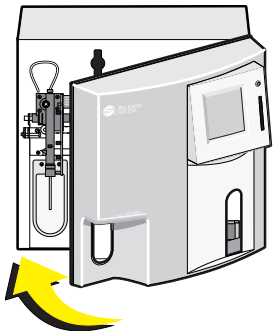
14 Slide the clip into the groove of the probe assembly to secure the probe wipe.



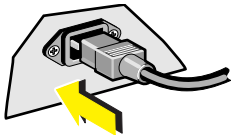
15 Push the probe all the way down until it is fully descended.



16 Close the front door.



17 Plug the instrument into its power source.



18 Turn the instrument on and resume normal operation.

19 Cycle a sample with known results to verify instrument's performance.

Replacing the Tube Holder

Tools/Supplies Needed

- ❑ Regular (flat) screwdriver

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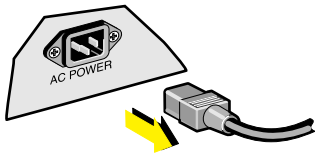
1 Turn off the instrument.

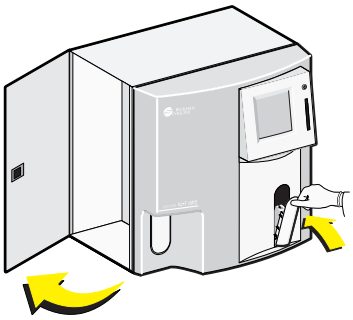
---

2 Unplug the instrument from its power source.

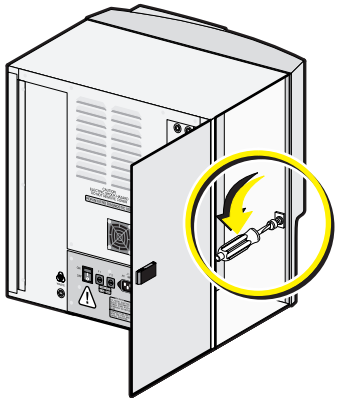


CAUTION Risk of instrument damage. If the instrument's front door is opened when the Cap Pierce door is open, the instrument may be damaged. Before opening the instrument's front door, verify that the Cap Pierce door is closed.

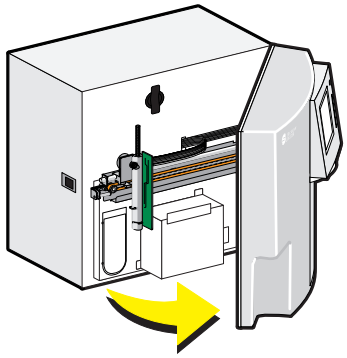
3 Open the left door.



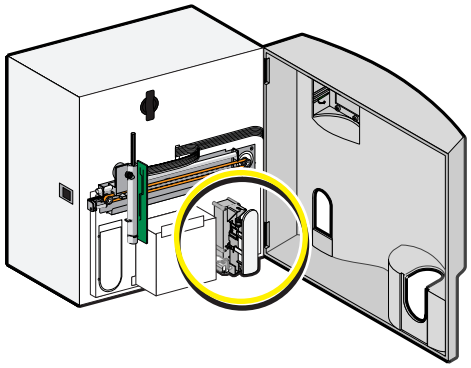
4 Use a regular (flat) screwdriver to turn the fastener that secures the front door.



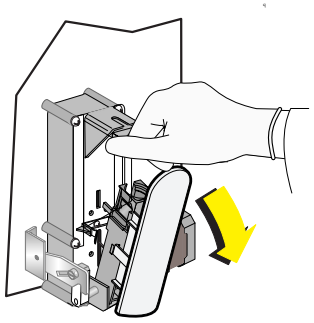
5 Pull the front door open.



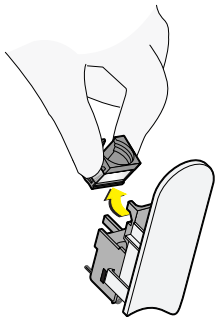
6 Locate the tube holder.



7 Open the tube holder door so that the tube holder is visible.



8 Pinch the clips together and slide the tube holder out of its slot.

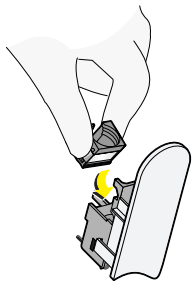


9 Properly dispose of the tube holder.

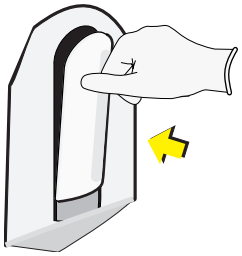
10 Insert the new tube holder:

a. Be sure the opening is towards the back of the instrument.

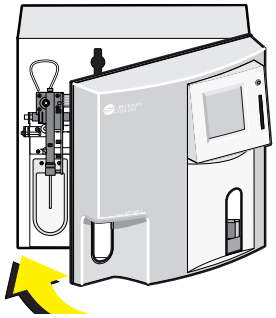
b. Snap the tube holder in place.



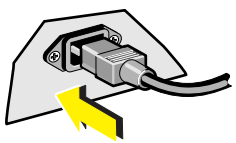
11 Close the tube holder door.



12 Close the front door.

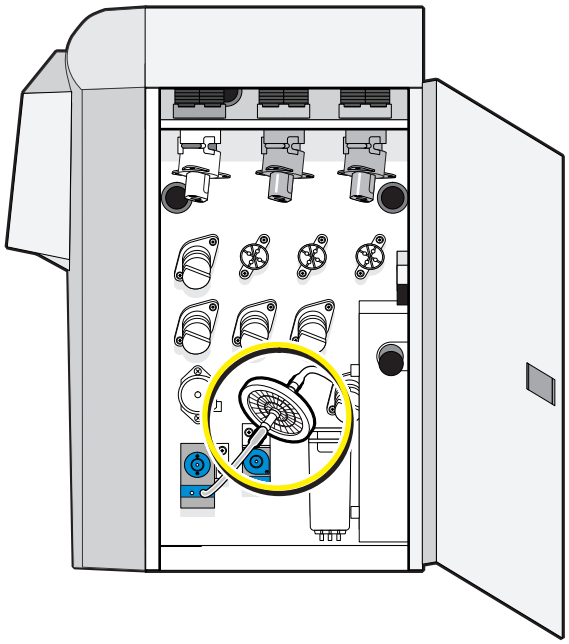


13 Plug the instrument into its power source.



14 Turn the instrument on and resume normal operation.

Replacing the Waste Filter

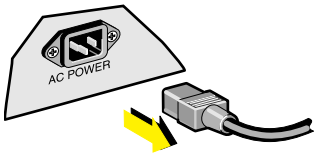


Tools/Supplies Needed

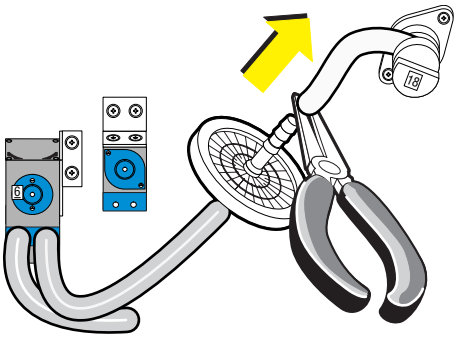
- ❑ Waste filter
- ❑ Pliers

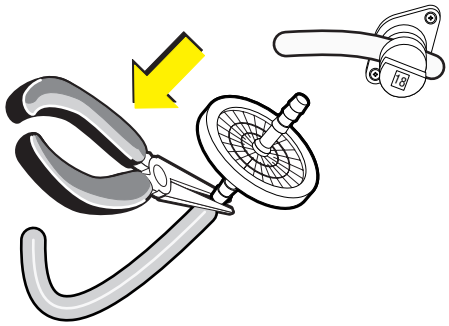
1 Turn off the instrument.

2 Unplug the instrument from its power source.



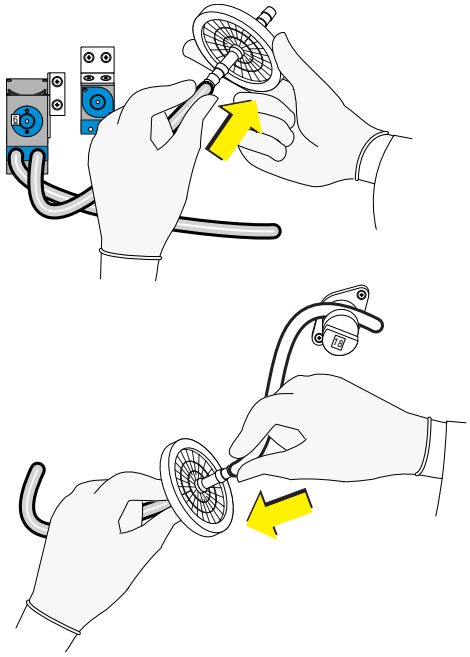
3 Remove the waste filter.



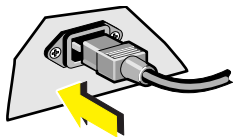


4 Properly dispose of the used waste filter.

5 Install the new waste filter.



6 Plug the instrument into its power source.



7 Turn the instrument on and resume normal operation.

6.7 PREPARING TO SHIP THE INSTRUMENT

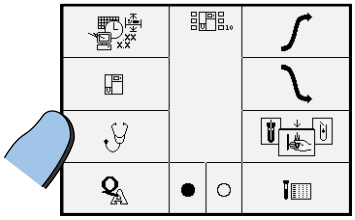
When you have done all the troubleshooting and still cannot fix the problem, call your Beckman Coulter Representative. **If directed to**, follow the authorization procedures and prepare the instrument for shipment as follows.

Two containers, bleach, distilled water, and paper towels are needed for this procedure.

CAUTION Risk of instrument damage. If the instrument remains dormant for extended periods of time without the appropriate Startup, Shutdown, or Prepare to Ship functions being performed, the fluid metering pumps may dry out and become damaged. When preparing the instrument for shipping, you must carefully follow all recommended procedures for Startup and Shutdown as noted in the following procedure.

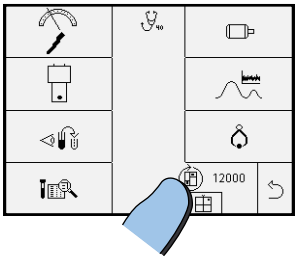
---

1 At the Main screen, touch the **Diagnostics** icon.



---

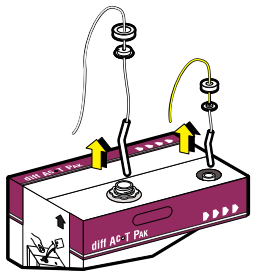
2 At the Diagnostics screen, touch the **Prepare to Ship** icon.



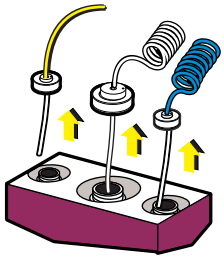
WARNING Instrument tubing can contain biohazardous material that can cause contamination if not handled properly. Handle these components according to acceptable laboratory practices.

3 Remove the diluent and lytic reagent pickup tubes from the reagent containers.

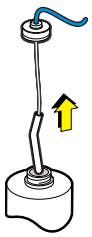
- For diff A^{C}•T Pak reagent, remove both pickup tubes



- For diff A^{C}•T Tainer reagent, remove all three pickup tubes

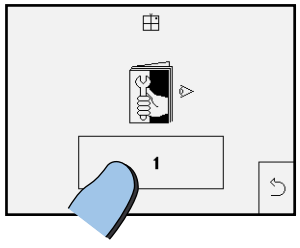


4 Remove the pickup tubes from the A^{C}•T Rinse shutdown diluent container, if using the diff A^{C}•T Pak reagent.

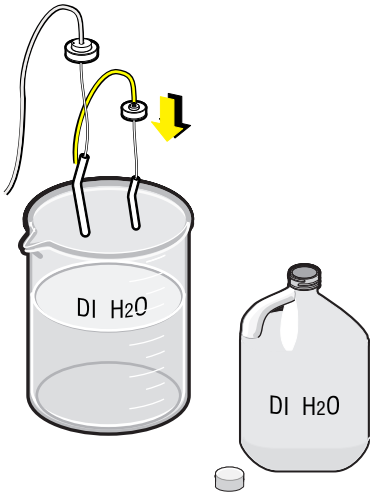


5 Touch the **1** to continue.

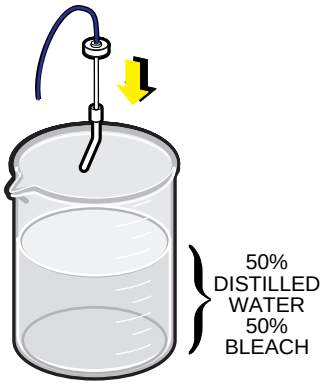
This process takes approximately 2 minutes.



6 Place the diluent and lytic reagent tubes upright in a deep container filled with distilled water.

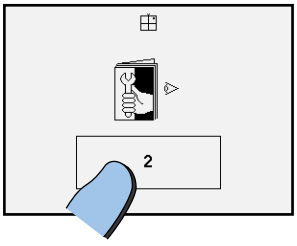


7 Place the rinse tube upright in a deep container filled with a 50% bleach-50% distilled water solution.

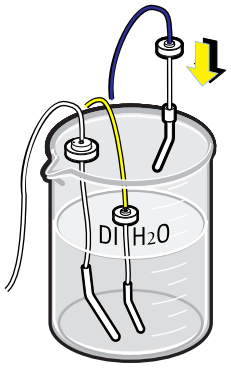


8 Touch the **2** to continue.

This process takes approximately 15 minutes.

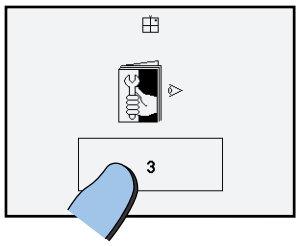


9 Remove the A^{C}•T Rinse shutdown diluent pickup tube from the bleach and place it with the others in distilled water.

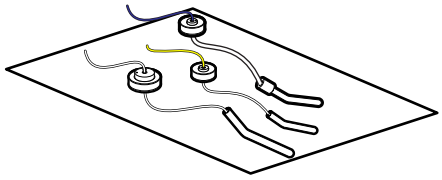


10 Touch the **3** to continue.

This process takes approximately 2 minutes.

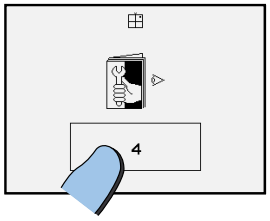


11 Remove the tubes from their respective solutions and place them on a paper towel to dry.

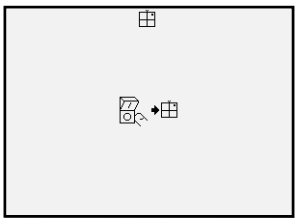


12 Touch the **4** to continue.

This process takes approximately 4 minutes, 15 seconds.



13 When the Ready to Ship screen appears, the instrument is cleaned out and decontaminated.



14 Turn the instrument off.

15 Prepare to decontaminate the waste tubes and sensor:

a. Remove the waste tubes and sensor from the waste container.

b. Squirt the waste tubes with a bleach solution to decontaminate.

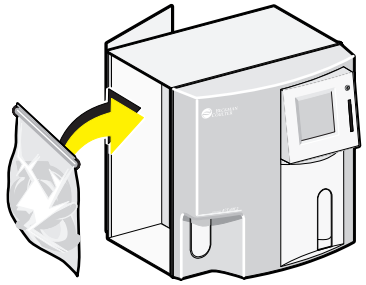
16 Disconnect the reagent and rinse pickup tubes from the instrument and pack them with the instrument.

17 Tightly seal all reagent containers.

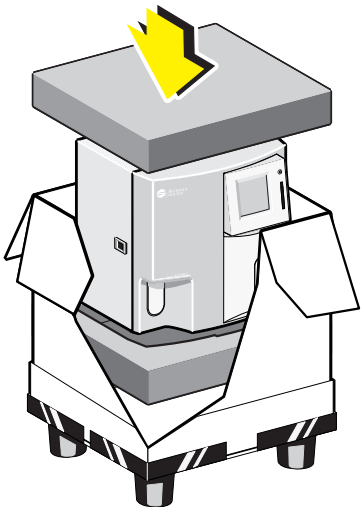
18 Remove the reagent management card from instrument and put back into the card slot on the reagent container box.

19 Disconnect all cables (power, printer) from the instrument.

Pack them with the instrument.



20 Pack the instrument in its original box.



21 Ship the instrument to the address obtained from your Beckman Coulter Representative.

6.8 TROUBLESHOOTING

Troubleshooting Tools

Knowing what your A^{C}•T diff 2 analyzer does, how it sounds when operating properly, and what normal results look like are the keys to troubleshooting problems. Study the Normal Sample Flow. Then watch and listen while the instrument goes through its cycles.

If you later find that your A^{C}•T diff 2 analyzer is not operating properly, you can begin to isolate the problem by studying irregular results (Table 6.10) and watching the instrument cycle a sample.

Diluter Functions

The Diluter Functions screen provides you with basic diluter functions to use in troubleshooting. Table 6.2 describes the diluter functions

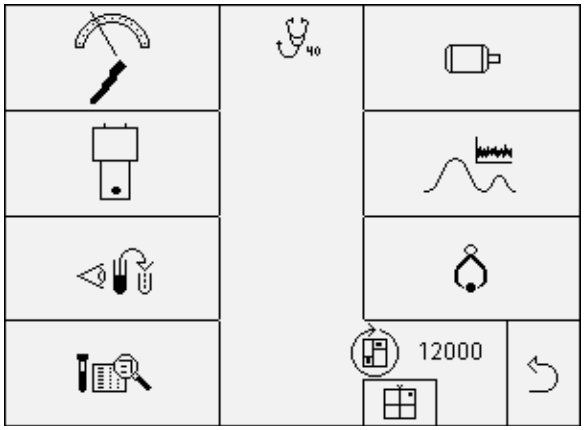


Table 6.2 Diluter Functions Screen

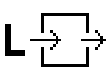
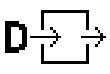
Icon	Description	Function
	Wet Prime	Primes the diluent fluidic path and baths. Dispenses lytic reagent to WBC bath. Removes air from diluent and lytic reagent lines.
	Sweepflow	Primes the fluidic path from the diluent reservoir through the sweepflow coil and the path between the RBC aperture and the vacuum isolator chamber.
	Automatically drains the baths then, after you aspirate bleach, cleans the baths.	Cleans the baths with a solution other than COULTER A^{C}•T Rinse cleaning agent (see Cleaning (Bleaching) the Baths). If the zap aperture function does not work, this is the third attempt (after Shutdown) to clear a clogged aperture.
	Primes the lytic reagent system when the A^{C}•T diff analyzer is first installed or reinstalled after being drained.	Primes the lytic reagent path of the fluidics system. Fills the lytic reagent path completely even if it is empty.
	Primes the diluent system.	Primes pickup tube and diluent reservoir. Fills the diluent path (between the diluent container and the diluent reservoir) completely, even if it is empty.

Table 6.2 Diluter Functions Screen *(Continued)*

Icon	Description	Function
	Drains the baths and the vacuum isolator chamber.	Drains fluid before you remove the baths or the vacuum isolator chamber. Verifies the operation of the waste pump.
	Primes the diluent reservoir system and fills both baths with fresh diluent. Sends mixing bubbles to each bath in turn.	Verifies operation of the rinse pump. Helps detect a plugged filter. Checks the operation of the diluent pump if you use it enough times to force a refill of the reservoir. Verifies operation of air/mix system. Helps detect plugs or leaks in the fluid barrier.
	Performs an aperture burn or zap.	Attempts to clear a plugged aperture, perform several times.
	Dispenses lytic reagent into the WBC bath.	Manually primes the lytic reagent system. Checks for bubbles in the lytic reagent system. Verifies the operation of the lytic reagent pump.
	Exits from the Diluter Functions screen.	Returns to previous screen.

Diagnostic Functions

The Diagnostic Functions screen provides you with basic diagnostic functions to use in troubleshooting. Table 6.3 describes the diagnostic functions.

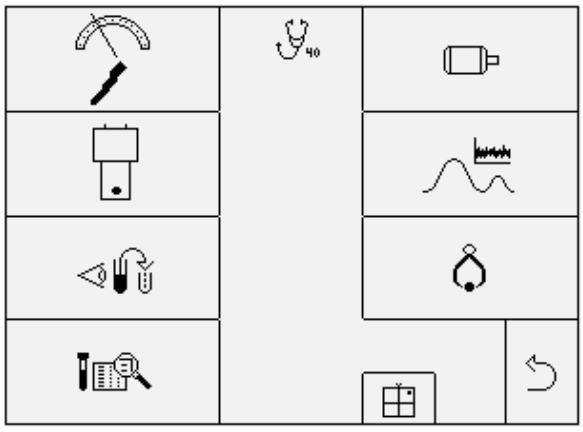
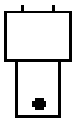
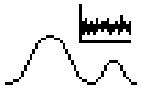


Table 6.3 Diagnostic Functions Screen

Icon	Description	Function
	Displays current state of digital sensors and current value of analog sensors and voltages.	Lets you adjust to 6.00 vacuum. Lets you verify correct sensor readings.
	Displays solenoids screen and allows you to change the state (ON or OFF) of each solenoid and DC motors.	Lets you test solenoid functions and DC motors. Indiscriminate use of these functions can damage the instrument. Do not use the motors function without instruction from your Beckman Coulter Representative.
	Displays verify predilute screen.	Lets you verify that the instrument is dispensing 4000 µL of diluent. Creates prediluted sample.
	Displays details of the last sample run screen.	Lets you troubleshoot aperture problems.
	Displays motors screen and allows you to interactively run each motor through its normal range of motion.	Indiscriminate use of these functions can damage the instrument. Do not use the motors function without instruction from your Beckman Coulter Representative.
	Displays an in-progress screen and performs an electronics pulse test.	Lets you verify the electronic stability of the instrument for WBC and RBC apertures.
	Latex gain Calibration	Lets you set particle sizes for WBC, RBC, and Plt gains.
	Prepare the instrument for shipping.	Lets you drain and disinfect the instrument in preparation for shipping.
	Exits the Diagnostic Functions screen.	Returns to previous screen.

6.9 PARAMETER CODES AND FLAGS

Analyze samples within 24 hours of collection.

Report results immediately if there are no flags and if the results are within your reference ranges. Table 6.4 shows the parameter codes and flags that can appear with results. Also note:

- If any flag appears, review the results according to your laboratory's protocol.
- The cells of whole blood collected in EDTA undergo a process of equilibration. White blood cells of certain samples might take up to 30 minutes to reach this state of equilibration in the EDTA. Also, after 5 hours, cellular deterioration might start to occur. These samples might show increased flagging of differential parameters (1, 2, 3, M). If a sample that produces differential flags is less than 30 minutes old, reanalysis of the sample at a later time might eliminate the differential flags.

Whole blood samples processed between 30 minutes and 5 hours of collection provide the best differential performance for all sample types, collection devices, and collection variables.

Prediluted samples processed between 5 minutes and 1 hour of collection provide the best differential performance for all sample types, collection devices, and collection variables.

Hierarchy of Flags

There are two types of flags:

- Those that **replace** the parameter results, also known as codes, and
- Those that **appear next to** the parameter results. Up to two of these flags can be displayed for a parameter.

Replacement Flags (Codes)

For those flags that **replace** the parameter results, the hierarchy, in decreasing order of importance, is:

- - - - -

+++++

XXXXX

. . . . .

Non-Replacement Flags

For those flags that **appear next to** the parameter results, the hierarchy, in decreasing order of importance, is:

X

+

*****

1, 2, 3, 4, M (where M means multiple regions)

H or **L**

6.10 WHAT FLAGS AND CODES MEAN

Table 6.4 describes the flags and suggests actions you should perform when they appear.

Table 6.4 What Flags Mean

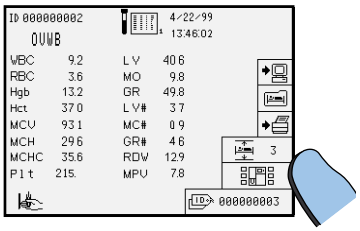
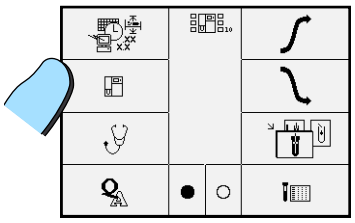
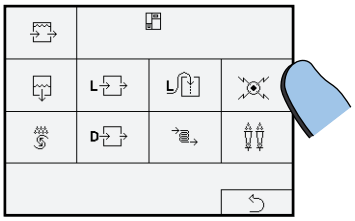
Flag/Code	Indication	Suggested Action
- - - - - (dashes)	Total Voteout. Replaces result when: • Two of the three count periods did not agree. • For WBC and RBC, the first count period votes out. You also see . . . . . for any parameter derived from a parameter replaced by - - - - -. If for WBC, also - - - - - for LY#, MO#, GR#, LY%, and * for MO%, and GR%. If for RBC, also . . . . . for Hct, MCH and MCHC, and * for MCV, RDW, Plt, MPV, (Pct and PDW). If for MCV, also . . . . . for Hct and MCHC, and * for RDW. If for Plt, also . . . . . for MPV (Pct and PDW). If for MPV, also * for Plt (Pct and PDW). If for PDW, also * for Plt, MPV (and Pct).	1. Thoroughly mix and rerun the sample. 2. If the voteout repeats, zap apertures: a.  b.  c. 

Table 6.4 What Flags Mean *(Continued)*

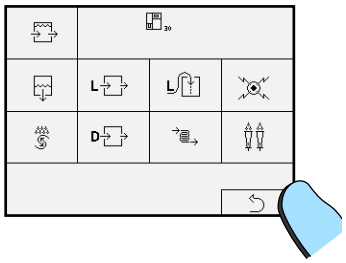
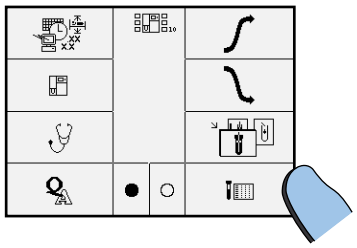
Flag/Code	Indication	Suggested Action
- - - - - *(continued)*		d.  e.  3. Thoroughly mix and rerun the sample. 4. If the voteout repeats, run a previously run sample with known values. 5. If the voteout repeats, clean the baths according to Cleaning (Bleaching) the Baths in this chapter. 6. Thoroughly mix and rerun the sample. 7. If the voteout repeats, call your Beckman Coulter Representative.

Table 6.4 What Flags Mean *(Continued)*

Flag/Code	Indication	Suggested Action
+++++ *(pluses)*	Results exceed operating range. • If for Plt, also **. . . . .** for MPV (Pct and PDW), and ***** for WBC, LY#, MO#, GR#, Hgb, MCH, MCHC. • If for Hgb, also **. . . . .** for MCH and MCHC. • If for RBC, * for MCV, RDW, Plt, MPV (Pct and PDW) and Hct; also **. . . . .** for MCH and MCHC. • If for WBC, also **. . . . .** for LY%, MO%, GR%, LY#, MO#, GR#; also ***** for RBC, Hgb, Hct, MCV, MCH, MCHC, RDW, Plt, and MPV (Pct and PDW).	For WBC, RBC, Hgb or Plt (if high sample result is possible: 1. Ensure that the bath shield is in place. 2. Make a dilution to determine the parameter result: a. Dilute 1 part thoroughly mixed sample with 1 part normal saline (0.85% NaCl) in a clean test tube. b. Mix then immediately run the dilution in whole blood mode. c. Multiply the parameter result by 2. Corrected result = (Dilution result x 2) d. Correct derived parameters if applicable. e. If result still gives **+++++**, increase dilution and repeat. If you suspect an instrument problem, run a sample or control with known results to determine the instrument problem: 1. Verify probe wash. 2. Verify lyse levels and delivery. 3. Verify diluent levels and delivery.
+++++	MCV <50 fL or >130 fL. • If for MCV <50, also ***** for RBC, MCH, RDW, Plt, MPV (Pct and PDW); also **. . . . .** for Hct and MCHC. • If for MCV >130, also ***** for RBC, MCH, RDW; also **. . . . .** for Hct and MCHC.	For MCV, verify results by alternative method, such as blood film review or spun Hct.
XXXXX	Aperture Alert. A problem was detected during counting that could compromise the integrity of the results. • If on WBC aperture, WBC and differential % and # show **XXXXX**. • If on RBC aperture, RBC, Hct, MCV, MCH, MCHC, RDW, Plt, MPV (Pct and PDW) show **XXXXX**.	1. Remove the stopper and gently mix the sample with a wooden applicator stick to check for fibrin strands or clots: • If fibrin strands or clots are found, collect and run a new sample. • If fibrin strands or clots are not found, thoroughly mix and rerun the sample.

Table 6.4 What Flags Mean *(Continued)*

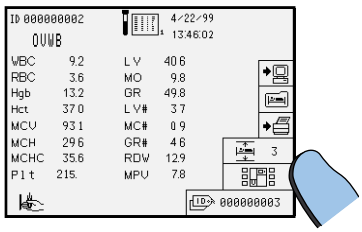
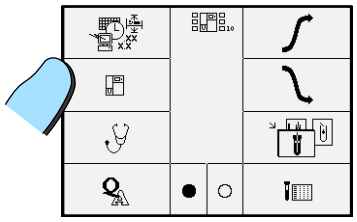
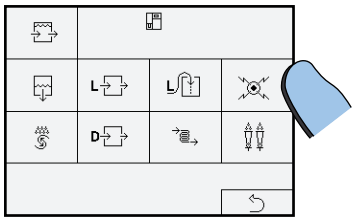
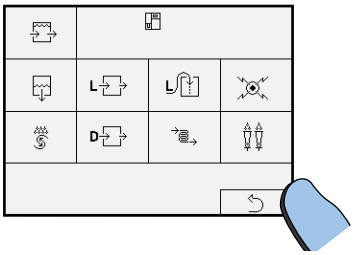
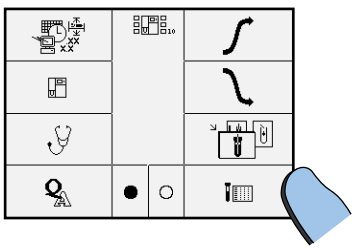
Flag/Code	Indication	Suggested Action
XXXXX *(continued)*		2. If the Aperture Alert repeats, run a previously run sample with known values. 3. If the Aperture Alert repeats, zap apertures: a.  b.  c.  d.  e.  4. Thoroughly mix and rerun the sample.

Table 6.4 What Flags Mean *(Continued)*

Flag/Code	Indication	Suggested Action
XXXXX *(continued)*		5. If the Aperture Alert repeats, clean the baths according to the Cleaning (Bleaching) the Baths procedure in this chapter. 6. Thoroughly mix and rerun the sample. 7. If the Aperture Alert repeats for a specific sample, use an alternative method. 8. If the Aperture Alert repeats for a specific sample, call your Beckman Coulter Representative.

Table 6.4 What Flags Mean *(Continued)*

Flag/Code	Indication	Suggested Action
. . . . . (dots)	Incomplete calculation. Result cannot be calculated. System does not have enough information to compute a result.	
	Parameter derived from parameter with a voteout (- - - - -).	See instructions for voteout (- - - - -).
	If for Hgb, error was detected during Hgb measurement, also . . . . . for MCH and MCHC. The Hgb Blank and/or Hgb Read results do not correlate.	1. Thoroughly mix and rerun the sample. 2. If Hgb . . . . . repeats, call your Beckman Coulter Representative. If on all samples: 1. Verify that Hgb lamp is illuminated. • If not, call your Beckman Coulter Representative. • If it is illuminated, run startup to set Hgb lamp voltage. 2. If problem persists, call your Beckman Coulter Representative. 3. If Hgb . . . . . repeats, call your Beckman Coulter Representative.
	If for Diff parameters: a. WBC <1.0 or >99.9 x 10^3/uL, b. WBC voteout (Diff # parameters only), or c. Result cannot be calculated.	If a): 1. Confirm results. 2. Do manual differential. If b), see instructions for voteout (- - - - -). If c): 1. Verify sample handling. 2. If this sample has been refrigerated, warm to room temperature then thoroughly mix and rerun sample. 3. Some samples require a longer than normal equilibration time. Wait 10 to 15 minutes, then thoroughly mix and rerun the sample. 4. If this sample is more than 5 hours old, collect a fresh sample or perform manual differential.

Table 6.4 What Flags Mean *(Continued)*

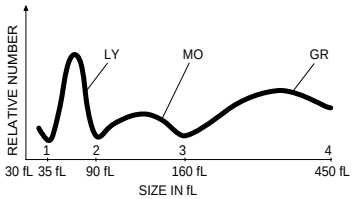
Flag/Code	Indication	Suggested Action
. . . . . (dots) *(continued)*	If for Hct, MCH and MCHC: a. RBC voteout (**- - - - -**), or b. RBC, Hgb, or MCV > Operating range (**+++++**), c. Hgb incomplete (error).	If a), see instructions for voteout (**- - - - -**). If b), see instructions for over operating range (**+++++**). If c), see Hgb above.
	If for MPV (Pct and PDW): a. Plt voteout. b. Plt over operating range.	If a), see instructions for voteout (**- - - - -**). If b), see instructions for over operating range (**+++++**).
	If for Hct and MCHC, MCV voteout.	See instructions for voteout (**- - - - -**).
+ (plus)	Overrange result. Indicates result is greater than linear range but less than operating range: WBC >99.9 <150 x 10^3/uL RBC >7.00 <8.00 x10^6/uL Hgb >25.0 <30.0 g/dL Plt >999 < 3000 x 10^3/uL	Verify results according to your laboratory's protocol. If any parameter is outside linearity limits, cycle diluent blank before proceeding with subsequent samples.
	If for WBC, also ***** for RBC, Hgb, MCV, Hct, MCH, MCHC, RDW, Plt, MPV (Pct and PDW), and **. . . . .** for LY#, MO#, GR#, LY%, MO%, and GR%.	
	If for RBC, also ***** for Hct, MCH MCHC, MCV, RDW, Plt, MPV, (Pct and PDW).	
	If for Plt, also ***** for MPV (Pct and PDW), WBC, LY#, MO#, GR#, Hgb, MCH, MCHC.	
	If for Hgb, also ***** for MCH and MCHC.	
1, 2, 3, 4, M	Differential parameters failed the internal regional size distributional criteria at one specific region (1, 2, 3 or 4) or multiple regions (M).  	Verify results according to your laboratory's protocol.
H	High result. For Patient samples, result is higher than the high patient sample limit. For Control samples, result is higher than the upper limit for that control sample.	Follow your laboratory's protocol.

Table 6.4 What Flags Mean *(Continued)*

Flag/Code	Indication	Suggested Action
L	Low result. For Patient samples, result is lower than the low patient sample limit. For Control samples, result is lower than the low limit for that control sample.	Follow your laboratory's protocol.
X	Review results. X flag indicates that one of the multiple Aperture Alert criteria was not met.	1. Thoroughly mix and rerun the sample. 2. If flag does not repeat, report result. 3. If flag repeats, clean the aperture as instructed in Zapping the Aperture. 4. If after cleaning, problem persists, contact your Beckman Coulter Representative.
*****	***** occurs on parameters influenced by **+++++**, **+**, - - - - - as detailed above.	See instructions for **+++++**, **+**, or - - - - - .
	If (Hgb g/dL x 3)/Hct% is <0.8 or >1.2 then RBC, Hgb, MCV, Hct, MCH, MCHC, Plt, MPV (Pct and PDW) are flagged with *. Possible sample handling problem.	
	If on RDW only, RBC histogram failed internal asymmetry check. Possible dual RBC population.	
	If on WBC and Differential only, 35 fL count interference check failed. Possible interference with WBC count.	
	If on Plt, MPV (Pct and PDW) only, Plt <20 $x10^3$/uL, or Platelet distribution failure Non-positive curve Mode <3 or >15 fL PDW >20 Voteout of fitted curve Sweepflow error	
	If MCHC <25.0 or >40.0 g/dL, then RBC Hgb, Hct, MCH, MCHC are flagged with *****. Possible sample interference or instrument problem.	

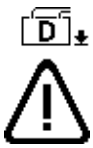
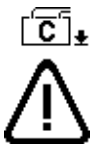
6.11 WHAT WARNING MESSAGES MEAN

Table 6.5 describes the warning messages and suggested recovery action.

Table 6.5 Warning Messages

Warning	Description	Suggested Action
	Printer is disconnected. Printer is not turned on. Printer is offline or out of paper.	Turn printer on and touch **printer** icon on the Sample Results screen to print. If you have no printer, check to see that auto-print is turned off (Print Profiles screen). See Setting Autoprint in Chapter 2.
	Transmission incomplete	Sample transmission to host failed. Touch the **transmission** icon on the Sample Results screen to retry the transmission. If transmission still fails, check communications cable to host and make sure that the host is online. Check that transmission settings are correct. If failure still occurs, power instrument off and then on. **Note**: You lose the ability to transmit a sample result when you power off the instrument.
	Vacuum failure	Go to voltage screen and try to adjust vacuum to 6.00. If it does not adjust: Make sure the pump is ON. Is there a leak associated with the Vacuum Isolator Chamber and associated tubing? Check all green striped tubing, front and right side. Is tubing connected tightly? Are there leaks? Is fluid barrier filter plugged? If yes, replace fluid barrier and adjust vacuum.
	Hgb voltage failure	Run a startup. Startup tries to adjust Hgb voltage. If it does not adjust: Make sure Hgb lamp is ON. Check for spillage around Hgb components on WBC bath. Make sure there is no diluent leak. (The baths fill.) Proper fluid level must be in the WBC bath at all times.
	High Plt count	Plt channel overrange. Acknowledge warning; instrument provides numeric results. Verify the results. Check for proper sweepflow operation with no bubbles. Check for sources of electrical interference. Check to ensure that bath shield is on. Check to ensure that Vacuum Isolator Chamber is clean and dry where the count drops appear.
	Time keeper failure	Reset the time and date. See Installing the Instrument in Chapter 2.
	Setup data corrupted	Check the setup values against your records. Correct the values, if necessary, and save. (See Customize Software in Chapter 2.) Print setup values. Run sample. **Note**: If data is corrupt on powerup, the data will be rewritten with the default data. Be sure to verify setup after this warning is displayed.

Table 6.5 Warning Messages *(Continued)*

Warning	Description	Suggested Action
	Control file full	There is no more storage space available for your 4C PLUS control files. If your laboratory is an IQAP participant, save the control data to a depleted reagent management card. See Heading 2.4, DOWNLOADING 4C PLUS CELL CONTROL RESULTS FOR IQAP. To make room for additional control file storage, you may want to delete some existing control files. See Heading 2.5, DELETING 4C PLUS CELL CONTROL FILES.
	Control expired	Do not use this control; it has expired. Use a control that is not expired.
	Patient data or control data corrupted	If this appears during startup, print what is currently stored to determine what patient data, if any, are present. Depending on the type of error, one or possibly all patient samples previously stored may be gone.
	Check A^{C}•T diff Reagent Management card	Make sure card is in reader correctly. If problem persists, it may be time for new reagent with a new card. If problem occurs with a new card, there could be a problem with the card, card reader, card reader connection, or card reader controller (which is part of the display assembly).
	Waste full	Do Replacing the Waste Container. Touch the **Continue** icon.
	Diluent empty	If reagent container does not appear empty, try priming first. If there appears to be reagent, but it does not fill properly, check for proper position of pickup tube, air leaks in tubing from cube to reservoir. Also check for crimps or plugs in the tubing from the reagent pickup to the bottom of the reservoir. These could affect reservoir fill. If reservoir is overfilled, replace diluent filters.
	Lytic reagent empty	If reagent container does not appear empty, try priming first. If there is lytic reagent in the lytic reagent container, make sure reagent pickup tubing is in fluid and that tubing and fittings are not leaking between reagent pickup and lytic reagent sensor. The lytic reagent sensor is located in the lytic reagent tubing.
	A^{C}•T Rinse Shutdown Diluent (cleaner) empty	If the cleaner container does not appear empty, try priming first. If priming does not work, make sure there are no leaks in any blue stripe tubing, beginning at the cleaning reagent pickup. Check the tubing connections to PM1, the tubing to LV18 and the tubing connections to the cleaning agent fluid sensor FS3.

6.12 SYSTEM ERRORS

Turn OFF the instrument, then turn it ON to see if the error is corrected. Table 6.6 offers some suggested actions. If these do not solve the problem, call your Beckman Coulter Representative.

Table 6.6 System Errors

 Number	Description	Probable Cause/Suggested Action
1	PCMCIA Error	Turn instrument OFF. Remove and reinstall software card. Turn instrument ON. If problem still exists, obtain new software card. If problem persists, call your Beckman Coulter Representative.
3	DVM Error	There is an instrument power supply failure or the power to the instrument is out of range. A temporary loss of power can also trigger the error. Try turning the instrument OFF/ON. Ensure that the power supply to instrument and power source are good. Ensure that fuses are good. If turning the instrument OFF/ON does not work, call your Beckman Coulter Representative.
4	Unexpected Software Condition	Turn instrument OFF. If this occurs, reseat the software card and turn ON the power. If the problem still persists, obtain a new software card. If problem persists, call your Beckman Coulter Representative.
6 7 8 9 10 11 19	Probe Did Not Reach Up Position Probe Did Not Reach Down Position Probe Did Not Reach Thief Position Probe Did Not Reach Closed Vial Position Probe Did Not Reach WBC Position Probe Did Not Reach RBC Position Probe Did Not Reach Open Vial Position	The Probe has 4 horizontal and 3 vertical probe positions. When the probe is sent to, but does not reach, a position, an error is generated describing the position that was not reached. Turn the power OFF and move the probe vertically and horizontally. Make sure there is no binding and there is nothing in the mechanism's path as it moves. Leave the probe in a central position horizontally and vertically. Turn the power ON. If the problem returns, check any probe movement that occurred. No attempt at movement indicates a motor or motor connection problem. Erratic motion could indicate a motor problem or a mechanism problem. Normal motion that seems to go into and past the proper position indicates a sensor or sensor connection problem. If problem persists, call your Beckman Coulter Representative.
12	Diluent Pump Did Not Reach Home	An attempt was made to home the diluent FMI pump. The home sensor was not seen.
16	I^2C (Internal Communication Failure)	Each motor in the instrument has its own microprocessor to control it. A problem has occurred with communication between the main and motor processors. When problems occur with this communication process, this error is generated. All the components in question are found on the Analyzer card. Turn instrument OFF then ON. If problem persists, call your Beckman Coulter Representative.

Table 6.6 System Errors *(Continued)*

 Number	Description	Probable Cause/Suggested Action
	Insufficient vacuum at beginning of cycle.	Leak or plug in vacuum system or problem with vacuum pump. Ensure that the vacuum pump is ON. Check the vacuum isolator system for leaks, plugs or fluid buildup. Ensure that there are no plugs near the vacuum source, such as a plug in the fluid barrier (green striped). Other problems may be with the pneumatic solenoids or vacuum sensor.Turn instrument OFF then ON. If problem persists, call your Beckman Coulter Representative.
20	Sample Pump Did Not Reach Home	An attempt was made to home the sample FMI pump. The home sensor was not seen.
21	Lyse Pump Did Not Reach Home	An attempt was made to home the lyse FMI pump. The home sensor was not seen.

6.13 TROUBLESHOOTING GUIDES

Tables 6.7 through 6.10 are troubleshooting guides. Each table details problems/situations, states the probable causes, and suggests actions for solving the situations.

Table 6.7 Power Problems

Situation	Probable Cause	Suggested Action
Screen is dark Power LED is lit.	A^{C}•T diff 2 analyzer dims the screen if you do not use the instrument for 15 minutes and also requires a prime if you do not use it for 2 hours.	Touch the screen to brighten it. If the **continue** icon appears in the status field, touch it to prime the system.
Power will not turn on.	Power cord loose or not securely connected to wall or instrument. Turn power OFF. No voltage or wrong voltage at laboratory power outlet. Defective power switch. Instrument malfunction.	Make sure power cord is securely connected to instrument and wall. Turn power ON. Make sure voltage is on and outlet is 90-264 Vac. Fuse is blown. Replace according to the Replacing Fuses procedure. Call your Beckman Coulter Representative. Call your Beckman Coulter Representative.

Table 6.8 Aspiration Problems

Situation	Probable Cause	Suggested Action
No aspiration takes place	1. Tubing Problem. Plug or leak in tubing from aspirate probe to aspirate pump.	1. Inspect tubing for leaks, kinks or plugs. Also inspect tubing to LV11 and LV12. .
	2. Problem with connection to sample pump.	2. Check to see that the connector to the 50 µL sample pump is tight and there is no air in the tubing or syringe.
	3. The sample pump is not working.	3. Leave pump, and check for motor movement when aspiration should be occurring.
Incomplete aspiration	It is very difficult to tell an incomplete aspiration when you are aspirating only 12 µL. This conclusion can only be arrived at by analyzing the results. WBC, RBC, Hgb and Plt would have to be low, with MCV normal.	Check for the same problems as above. They will be partial leaks or plugs instead of pulled-off tubes or total plugs.
Sample drips from probe after aspiration.	1. Fluid drips from inside the probe.	1. This is a leak in the aspiration pathway. Check the same tubing and components as above for leaks.
	2. Fluid drips outside the probe.	2. The probe wipe is not working. Check for leaks in the tubing to the probe wipe, a plug in the lower waste port of the probe wipe, a plug in the tubing between the lower probe wipe port and the Vacuum Isolator Chamber, a vacuum leak at the Vacuum Isolator Chamber, or no vacuum. Check to ensure that the vacuum pump is turned on and is working. (Vacuum pump is in right side door.)
Bubbles in aspirator tubing between tip and aspirator pump.	1. Leak from sample pump to aspirate tip.	1. If air is in these lines, check the components and tubing for partial or no aspiration. Check for leaks in pinch tubing at LV8.
	2. Leak between diluent reservoir and aspiration pump assembly.	2. A leak from the reservoir to the sample pump assembly will cause air to be in the line to the aspirate probe. This would involve the tubing and the sample pump.

Table 6.9 Background Problems

Situation	Probable Cause	Suggested Action
WBC, RBC and Plt exceed limits. Hgb may also be high in noted instances.	1. Contaminated diluent.	1. Replace diluent. Do a prime and startup. If you suspect biological contamination, perform Heading 6.7, PREPARING TO SHIP THE INSTRUMENT. This allows you to cycle bleach through all appropriate tubing and components.
	2. Contaminated baths. This can be caused by a cleaning solution left in the baths for an extended period of time.	2. Run several startups to remove any contamination. Perform the Cleaning (Bleaching) the Baths procedure (under Heading 6.3).
	3. Many bubbles in both baths.	3. Check the system for bubbles, starting with the fluid reservoir and moving on to the sample and diluent pumps. Remove the bath shield and run a cycle, observing the fluid in the baths if necessary. Repair any leaks that have caused the bubbles, whether tubing, fitting, or component.
	4. Blood in the aspiration path before the background aspiration. The instrument guards against this and any problem that circumvents the system would usually cause some other error on the previous cycle.	4. Do high/low carryover checks (see Heading 6.4). Backgrounds should pass or be very close on the first blank. If they are high and then fall on subsequent cycles, there could be blood left over from the previous cycle.
	5. Electrical interference. This will usually affect only the counts, not Hgb	5. Ensure that the bath shield is on the plate that the baths are mounted to, including the bath shield, is not connected to the main instrument. 6. Ensure no electrical connection is made, including salt buildup that could connect the shield or plate to the main instrument chassis. 7. Ensure there are no fluid spills in and around the bath area. 8. Ensure that no electrical equipment, especially motorized equipment, is operating near the instrument. Check the power source. Check that no motorized piece of equipment is plugged into the same power circuit. 9. Ensure that the ground connection at the outlet is good.

Table 6.9 Background Problems *(Continued)*

Situation	Probable Cause	Suggested Action
Only WBC results exceed background specifications.	1. Contamination to a smaller degree than above.	1. Redo startup. Proceed as above if problem persists.
	2. Bubbles in bath. Since only WBC is affected, the source is either incorrect mixing bubbles to the WBC bath or air in the lytic reagent system.	2. Check the bath during count for excessive mixing bubbles. Check the lytic reagent (yellow tubing) system for leaks, air bubbles.
	3. Electrical interference. This generally affects WBC and/or Plt first, since they normally produce smaller count pulses than the RBC.	3. See above. Problem could also be with WBC bath/aperture assembly, connection to the Analyzer card, or the Analyzer card itself.
Only RBC results exceed background specifications.	1. Excessive mixing bubbles.	1. Check green stripe tubing to bottom of RBC bath for partial obstructions and replace the tubing, if necessary.
	2. Air in sweepflow. This may also affect Plt backgrounds.	2. Perform a sweepflow prime. Watch the tubing in the sweepflow spool for air bubbles. If the line does not prime, look for air leaks in the tubing from the reservoir to the sweepflow tubing.
Only Plt results exceed background specifications	1. Plts are the smallest pulses measured. Any problem that affects all the other count parameters will affect Plts first. Depending how bad the problem is, only Plts may be affected. This includes contamination, bubbles, sweepflow problems, and electrical interference.	1. See above.

Table 6.10 Irregular Sample Results

Situation	Probable Cause	Suggested Action
All counted parameters are consistently lower than normal. MCV is normal.	1. Short sample. 2. Poor bath drain. 3. Diluted sample.	1. See aspiration problems in Table 6.8. 2. Leaks or plugs are in drain path. LV12, LV15, or LV18 has a problem. Plugged filter to waste pump. Waste pump has a problem. 3. Check that probe wipe is working and not dripping into sample. See aspiration problems in Table 6.8.
All counted parameters are consistently higher than normal. MCV is normal.	1. Incomplete probe wipe. 2. Insufficient diluent for dilution.	1. Check for signs of blood left on probe at end of cycle. Check for blood left at lower probe wipe fitting when probe has just retracted. 2. Check for air in diluent path from the sample or diluent pump, to probe and to side fitting at bottom of bath. Check for diluent leaks at bottom of WBC bath.
All counted parameters are consistently higher than normal.	1. Contamination 2. Electrical interference	1. See high backgrounds in Table 6.9. 2. See high backgrounds in Table 6.9.
WBC and Plt are too high or low, Hgb and RBC are opposite, too low or high.	Sample was not mixed adequately before aspiration.	Remix sample and cycle again.
Parameters generally erratic with no specific high/low trend.	Poor or no mix bubbles in bath.	Check green striped tubing at bottom of baths for leaks or plugs. Inspect or replace the check valves in these lines. LV3 and LV4 may have problems. They are at the other end of the green striped tubing.
Samples run in Predilute mode have erratic parameters.	Incorrect or contaminated predilute dilution.	Verify predilution. Make a dilution using larger volumes or use the **Verify Predilute** icon in the Diagnostics Function screen.
WBC results are higher than normal.	1. Insufficient lytic reagent. 2. Insufficient mix bubbles to WBC dilution. 3. Electrical interference. 4. Cracked aperture. This will generally cause WBC Aperture Alerts before the affect to results is noticeable.	1. Air bubbles or leak in lytic reagent system. Check reagent lines as above. 2. Check for mixing bubbles after lytic reagent has been added. These bubbles enter lower right side port of WBC bath. Check the green stripe tubing, the check valve in this tubing, and LV4. 3. See electrical interference and backgrounds in Table 6.9. Do a background and see if it passes. 4. Replace WBC aperture bath assembly.
WBC and Hgb results are higher than normal.	Insufficient lytic reagent in dilution. More severe case than above. Will get WBC voteouts or Aperture Alerts frequently.	Check for insufficient lytic reagent as above.

Table 6.10 Irregular Sample Results *(Continued)*

Situation	Probable Cause	Suggested Action
WBC results are lower than normal.	1. Protein buildup on aperture.	1. Perform several zap aperture functions from the Diluter Functions screen. If this is not sufficient, bleach the apertures and baths using the **clean baths** icon from the Diluter Functions screen (in the Diluter Functions section of this chapter).
	2. Problem with vacuum draw to aperture. This will cause an Aperture Alert before the results are noticeably low.	2. Check the red stripe tubing leaving the rear of the bath, going to LV17, and going from LV17 to the VIC. A plug in LV17 or in the fitting entering the VIC is also a possibility.
Hgb results are erratic.	1. Fluid in optical path outside of bath.	1. Check for fluid and salt deposits on outside of bath and Hgb components. Remove, clean and dry, if necessary. If there is fluid, find the source and repair if necessary.
	2. Bubbles in blank rinses. Blanks are taken on the rinse that is in the bath before aspiration takes place and the WBC prefill. The prefill will be more suspect.	2. The diluent rinse and dilution prefill come from the diluent FMI pump. Correct any leaks and air in this system.
	3. Abnormal sample interfering with Hgb.	3. Run several other samples to see if problem is unique to original sample.
RBC, MCV and Plt are affected.	1. Inadequate mixing or bubbles remaining during count.	1. Check for mixing bubble problems or leaks in the diluent path from the pump to the bath and probe. See above.
	2. Sweepflow problem.	2. Perform the Sweepflow function from the Diluter Functions screen (see Table 6.2). Ensure that fluid moves in the sweepflow system and that all bubbles have been removed.
RBC, Plt incorrect	1. Dilution problem.	1. Air in diluent, possible leak. See above.
	2. Aspiration problem.	2. Air in aspiration path after sample delivered to WBC bath, causing aspiration problems for RBC aspiration. RBC dilution aspirates fluid from WBC bath after initial delivery and mix. If level in bath is too low, or probe barely reaches level, results are low.
	3. Aperture sampling problem.	3. Partial plug or leak in aperture area, red tube from rear of bath to Vacuum Isolator Chamber (VIC), LV16, or tubing port on VIC. A severe blockage or leak could cause an Aperture Alert.

Table 6.10 Irregular Sample Results *(Continued)*

Situation	Probable Cause	Suggested Action
MCV only incorrect.	1. Protein buildup on aperture, causing elevated MCV. If this problem gets worse, Plts and RBCs are affected. A high frequency of RBC Aperture Alerts occurs.	1. Perform the **Clean Baths** function from the Diluter Functions screen (see Cleaning (Bleaching) the Baths under Heading 6.3).
	2. Cracked aperture resulting in low MCV. If the crack is bad, RBC Aperture Alerts will occur. Also the RBC and Plt counts will increase.	2. If this is the problem, you must replace the RBC aperture bath. Call your Beckman Coulter Representative.
Plt only incorrect	1. Electrical interference. Since Plts produce the smallest pulses analyzed by the system, low level electrical interference affects Plts only.	1. See electrical interference under background problems, Table 6.9.
	2. Contamination by small particles could also affect Plts only. This is not common, since contamination usually involves a wide size range of particles.	2. Change diluent. If the instrument is badly contaminated, especially with biological growth, run the Prepare to Ship procedure from the Diagnostic Functions screen.
	3. Fluid in sweepflow, but sweepflow is not moving. This could be a plug or an air lock that low vacuum cannot break.	3. Perform the Sweepflow prime from the Diluter Functions screen. This function primes the sweepflow with high vacuum. Make sure that fluid is moving. If not, a plug or a leak in the sweepflow check valve could be the problem.
Whole blood results similar to pattern below: WBC – – – – – x 10^3 cells/µL RBC **+++++** x 10^6 cells/µL Hgb **+++++** g/dL Hct **+++++** % MCV **+++++** fL MCH 40 pg MCHC 15 g/dL Plt 0 x 10^3 cells/µL	Undiluted whole blood was analyzed in the **Predilute** mode.	Select **Whole Blood** mode and rerun the patient sample. Clean aspirate system by doing primes and/or Startup.

A.1 ANALYSIS PROCEDURE

Use a material with known reference values as your calibrator.

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1 Be sure you have done Precalibration Checks, Reproducibility, and Carryover. See Chapter 5 for details.

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2 Prepare your material as needed.

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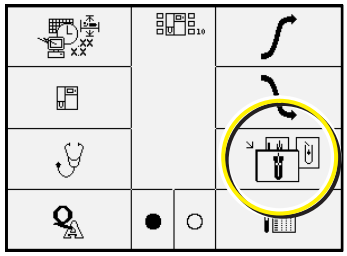
3 At the Main screen, select the **Closed Vial Whole Blood** mode.



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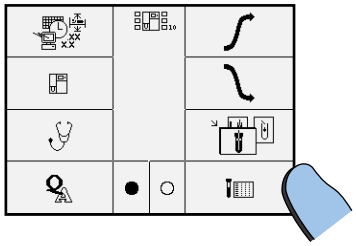
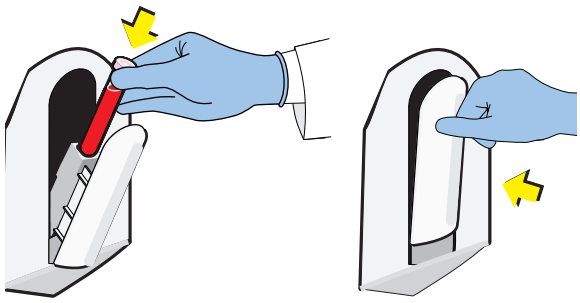
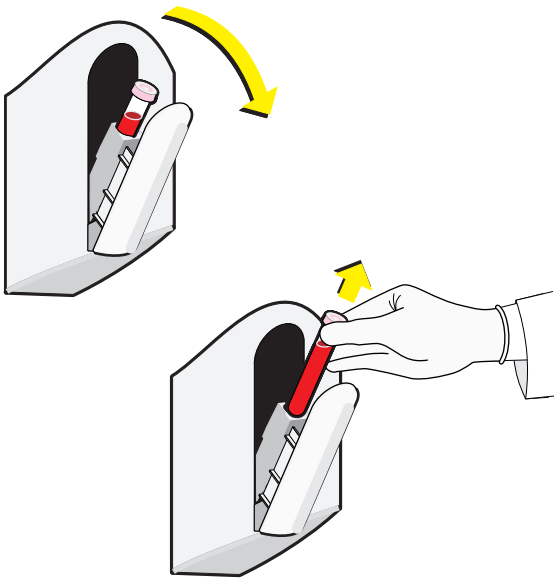
4 At the Main screen, touch the **Sample Results** icon.



5 Place the well-mixed material in the tube holder and close the door.



6 When the door opens, remove the tube from the tube holder.



7 Record the results on the calibration worksheet.

CALIBRATION WORKSHEET

Sample Number	WBC	RBC	Hgb	MCV	Plt
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
TOTAL					
MEAN (A)					
ASSIGNED VALUE (B)					
ABSOLUTE DIFFERENCE (C)					
CALIBRATION REQUIRED					
CURRENT CALIBRATION FACTOR (D)					
NEW CALIBRATION FACTOR (E)					

C = B - A
E = (B / A) x D

8 Repeat steps 4 and 5 ten times, for a total of 11 runs.

9 Do the Heading A.2, CALCULATIONS PROCEDURE.

A.2 CALCULATIONS PROCEDURE

1 Calculate the mean for each parameter using samples 2 through 11 on the worksheet. Write this number into row A on the worksheet.

2 Copy your calibrator material's assigned value to the worksheet. Write this number into row B on the worksheet.

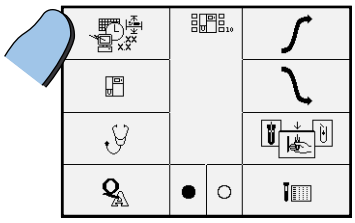
3 Calculate the absolute difference between the assigned value and the mean value calculated in step 1. Write this number into row C of the worksheet.

4 Determine if calibration is necessary by comparing the absolute difference from row C to your material's calibration criteria table.

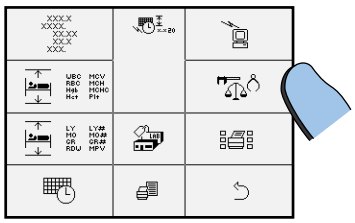
- If the absolute difference is less than the value in your material's calibration criteria table, no calibration is required.
- If the absolute difference is between the values found in your material's calibration criteria table, do Calculating New Calibration Factors.
- If the absolute difference is greater than the value found in your material's calibration criteria table, eliminate possible instrument problems and possible calibrator deterioration. If you determine calibration may be needed, call your Coulter Representative before calibrating.

A.3 CALCULATING NEW CALIBRATION FACTORS

1 At the Main screen, touch the **Setup** icon.



2 At the Setup screen, touch the **Calibration Factors** icon.



3 Record these factors into row D on the worksheet.

4 Calculate the new calibration factor using this formula:

$$\text{new calibration factor} = \frac{\text{assigned value (B)}}{\text{mean value (A)}} \times \text{current calibration factor}$$

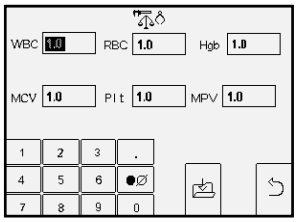
a. Divide the assigned value (row B) by the mean value (row A).

b. Multiply the derived number from step a by the current calibration factor (row D).

c. Record the new calibration factor into row E of the worksheet.

5 Enter the new values on the Calibration Factors screen.

Save the new values by touching the **Save** icon.



6 Verify that calibration is acceptable:

a. Analyze a material with known values, such as 4C PLUS cell control.

b. Be sure that the results fall within the expected ranges. If they do not, run one more sample.

c. If the results still do not fall within the expected ranges, call your Coulter Representative.

Calibration Worksheet

Sample Number	WBC	RBC	Hgb	MCV	Plt
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
TOTAL					
MEAN (A)					
ASSIGNED VALUE (B)					
ABSOLUTE DIFFERENCE (C)					
CALIBRATION REQUIRED					
CURRENT CALIBRATION FACTOR (D)					
NEW CALIBRATION FACTOR (E)					

A = samples 2 through 11
C = B - A
E = (B / A) x D

B.1 TUBES

Table B.1 lists the tubes and tube adapters approved for use with the A^{C}•T diff 2 analyzer.

Table B.1 Closed Vial Sample Tubes

Tube Manufacturer and Name	Product Number	Fill Volume (mL)	Dimensions (mm) (O.D. x Length x Pierce Diameter)
Becton-Dickinson VACUTAINER®	6405	2.5	12.2 x 80 x 6.0
Becton-Dickinson VACUTAINER	6458	3.5	15.2 x 80 x 6.0
Becton-Dickinson VACUTAINER	6545	4.0	15.2 x 80 x 6.0
Becton-Dickinson VACUTAINER	6452	5.0	12.2 x 80 x 6.0
Becton-Dickinson HEMOGARD™	367651	2.0	12.2 x 80 x 6.0
Becton-Dickinson HEMOGARD	367653	5.0	12.2 x 80 x 6.0
Becton-Dickinson HEMOGARD	367658	5.0	12.2 x 80 x 6.0
Becton-Dickinson HEMOGARD	367661	3.0	12.2 x 80 x 6.0
Becton-Dickinson HEMOGARD	367662	5.0	12.2 x 80 x 6.0
Becton-Dickinson HEMOGARD	367841	2.0	12.2 x 80 x 6.0
Becton-Dickinson HEMOGARD	367842	2.0	12.2 x 80 x 6.0
Becton-Dickinson HEMOGARD	367856	3.0	12.2 x 80 x 6.0
Becton-Dickinson HEMOGARD	367859	3.0	12.2 x 80 x 6.0
Becton-Dickinson HEMOGARD	367861	4.0	12.2 x 80 x 6.0
Becton-Dickinson HEMOGARD	367862	4.0	12.2 x 80 x 6.0
Coulter Corporation 4C	4C	3.0	12.7 x 66 x 5.0
Greiner VACUETTE®	454087	2.0	12.2 x 80.6 x 4.5
Greiner VACUETTE	454086	3.0	12.2 x 80.6 x 4.5
Greiner VACUETTE	454036	4.0	12.2 x 80.6 x 4.5
Kabe	E201N	1.8	11.5 x 60 x 3.2
Kabe	E301N	3.0	11.5 x 80 x 3.2
Labco Exetainer®	35241S140	3.0	12.2 x 82 x 7.0
Labco Exetainer	35271S159	5.0	12.2 x 82 x 7.0
Labo Express Service		4.0	
LDM	940712	5.0	
LDM	940713	5.0	
LIP	388873KE4/GL	4.0	
LIP	388872KE2.5/GL	2.5	
LIP	389082KE4/GL	4.0	12.2 x 84 x 7.6
LIP	389173KE4/GL	4.0	12.2 x 84 x 7.6
Sarstedt Monovette® w/Hollow Plastic Plunger	05.1167.100	2.7	11.5 x 81 x 5.0

Table B.1 Closed Vial Sample Tubes *(Continued)*

Tube Manufacturer and Name	Product Number	Fill Volume (mL)	Dimensions (mm) (O.D. x Length x Pierce Diameter)
Sherwood Medical	8881-314440	3.0	12.2 x 80 x 6.5
Sherwood Medical	8881-311446	5.0	12.2 x 80 x 6.5
Terumo VENOJECT®	T-206QS		12.5 x 80 x 5.0
Terumo VENOJECT	T-202SQS		15.5 x 80 x 5.0
Becton-Dickinson Microtainer w/Pierceable Cap*	365991	0.25 to 0.50	10.2 x 46 x 5.0
Becton-Dickinson MidRange w/False Bottom	368241 (Europe) 368247 (U.K./Asia) 368261 (USA)	2.0	11.5 x 81 x 6.0
Becton-Dickinson MidRange w/False Bottom	368242 (Europe) 368248 (U.K./Asia) 368262 (USA)	3.0	11.5 x 81 x 6.0

Blank indicates Not Available.
** indicates that Coulter Tube Adapter PN 1020854 is required.*

B.2 TUBE LIMITATIONS

- Except for Becton-Dickinson Microtainer w/Pierceable Cap (365991), all tubes should contain a minimum of 1 mL sample when running in the Closed Vial Whole Blood mode.
- Coulter recommends that the tubes in Table B.1 be run no more than 11 times each in Closed Vial Whole Blood mode.

The following sample tube types and general sample tube attributes (Table B.2) cannot be used with the A^C•T diff 2 analyzer:

Table B.2 Types of Tubes Not For Use with A^C•T diff 2 Analyzer

Tube	Tube Types
Sarstedt Monovette with a solid rubber plunger	• Tubes equivalent to the Sarstedt Monovette with a solid rubber plunger • Tubes with an outside diameter of >16 mm or <11.5 mm. • Tubes with length of >85 mm, including cap. • Tubes with length of <55 mm when measured from the tube bottom to the base of the cap. • Tubes with a pierce diameter of <3.2 mm. • Tubes with cap configurations that trap fluid on underside when the tube is oriented with the cap up.

B.3 TUBE ADAPTER

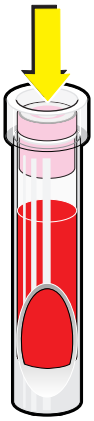
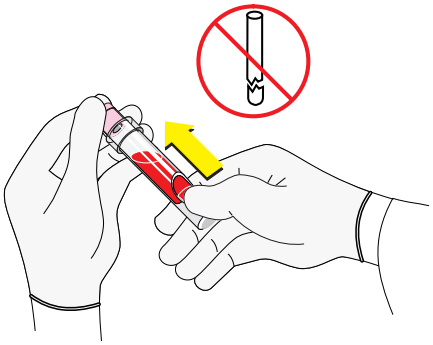
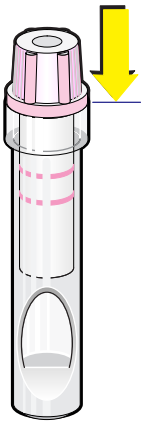
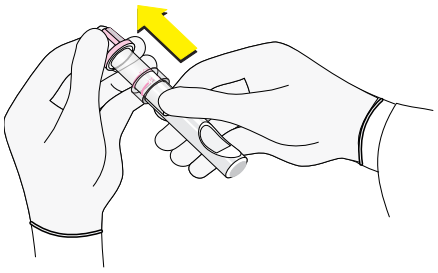
Certain tubes listed in Table B.1 require the use of the Coulter Tube Adapter.

The tube will either fit inside the tube adapter or the tube's cap will rest on top of the tube adapter. See Table B.3.

Note: Certain tubes will not fit into the adapter if more than two self-adhesive labels are applied in addition to the manufacturer's label.

Note: Coulter does not recommend the use of glass tubes with the Coulter Tube Adapter.

Table B.3 Tube Adapter Usage

Description	Illustration	Removing Tubes from Tube Adapter
Tube adapter with tube that fits entirely inside. 		
Tube adapter with tube that does not fit entirely inside; tube cap rests on top of adapter. 		

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Accuracy	Ability of the instrument to agree with a predetermined reference value at any point within the operating range; closeness of a result to the true (accepted) value.
Ambient	Surroundings or environment.
Assay	Procedure of repeat testing to determine the assigned value for a given lot and level of control.
Assay Values	Values of all parameters in a control established by extensive assay of that control.
Assigned Values	Values of all parameters in a calibrator established by extensive testing of that calibrator.
Aspirate-Verify Cycle	Aspirates 20 µL of whole blood.
Background Count	Measure of the amount of electrical or particle interference.
Background Cycle	Ensures that instrument is ready to run.
Baud	A rate defining how many data bits per second are transferred during communications between two pieces of equipment.
Blank Cycle	Runs diluent through the system to clean it out.
Calibration	A procedure to standardize the instrument by determining its deviation from calibration references and applying any necessary correction factors.
Calibration Factors	These are correction factors that the system uses to fine-tune instrument accuracy.
Calibrator	A substance traceable to a reference method for preparation or material used to calibrate, graduate, or adjust a measurement.
Carryover	The amount, in percent, of blood cells or Hgb remaining in diluent following the cycling of a blood sample.
Cell Control	A preparation made of human blood with stabilized cells and surrogate material. It is used for daily instrument quality control.
Clean Baths Cycle	You present bleach at the sample probe for aspiration into the baths; alternative to Shutdown.
Cleanup Cycle	Cleans up the system during powerup.
Closed Vial Mode	Primary sample analysis mode for processing samples that can be cap pierced.
Codes	On printouts, symbols such as +++++, -----, ..., +, * that appear **in place of** sample results. See Heading 9.18, WHAT FLAGS AND CODES MEAN for additional information.
Coefficient of Variation	An expression, in percent, of data (SD) spread as related to the mean. %CV = (SD / mean) 100
Coincidence	More than one cell within aperture sensing boundaries at the same time. The system senses these as one large cell rather than as two distinct cells, so it generates one large pulse.
Control	A substance used for monitoring the performance of an analytical process or instrument.
Coulter Histogram Differential (CHD)	How the computer computes absolute numbers for each population of LY, MO, and GR.
Coulter Principle	W.H. Coulter's method for counting and sizing cells and particles.
Conventions	Standard style or format used in a particular manual.
CV	(see Coefficient of Variation)
Data Bit	Computer code used to transfer each character of information.
Defaults	Original settings in the instrument. You can change these to tailor operation to your situation.
Diluter	Prepares the proper dilutions for sample analysis.
Dispense Diluent Cycle	Provides the proper amount of diluent for preparation of a prediluted sample.

Dispense Lyse Cycle	Dispenses lyse into the WBC bath.
Dispense-Verify Cycle	Dispenses proper volume of diluent for preparation of a prediluted sample with 20 µL of whole blood aspirated by the aspirate-verify cycle.
Drain Cycle	Drains the RBC bath, WBC bath, and the vacuum isolator chamber.
Dry Prime Diluent Cycle	Primes the pickup tube and diluent reservoir. Fills the diluent path between the diluent container and the diluent reservoir, even if empty; it does not fill the diluent path between the diluent reservoir and the baths.
Dry Prime Lyse Cycle	Primes the lyse path of the fluidics system; fills the lyse path completely, even if empty.
Expiration Date	The last day when you can use that lot number of reagent, control or calibrator.
fL	Abbreviation for femtoliters.
femtoliters	One quadrillionth (10^{-15}) of a liter.
Field	Area on a screen for entering data.
Flags	On printouts, letters (H, L, *, +) that appear **next to** parameter results to indicate specific conditions. See Heading 9.18, WHAT FLAGS AND CODES MEAN for additional information.
Hemoglobinometry	Measurement of hemoglobin in the blood. In COULTER instruments, this is done by comparing the amount of light that passes through a diluted lysed sample in which the released Hgb has been chemically converted, with the amount of light that passes through a blank.
Icon	Pictorial representation for commands or options on an instrument.
IQAP (Interlaboratory Quality Assurance Program)	Coulter Diagnostics, a division of Coulter Corporation, provides this program which statistically compares your 4C PLUS cell control data to a group of other laboratories' control recovery data.
Linearity	The ability of an instrument to recover expected results (reference values or calculated values) for such parameters as WBC, RBC, Hgb and Plt at varying levels of concentration of these parameters within specified limits.
Lot Number	A manufacturer's code that identifies when the reagent was manufactured.
Mean	Arithmetic average of a group of data.
Open Vial Mode	Secondary sample analysis mode for processing samples that required the cap to be removed.
Operating range	Range of results over which the instrument displays, prints, and transmits data.
Outlier	Control result that falls outside the expected range.
Parameters	Components of blood that the instrument measures and reports.
Parity	Method of detecting errors in data handling. The computer generates a parity bit such that the sum of the data bits and the parity bit are odd or even for each data word.
Performance characteristics	Actual performance of the instrument.
Performance specifications	Targeted performance of the instrument based on established ranges and parameters.
Powerup Cycle	Performs appropriate checks to ensure system is functioning correctly and prepares the instrument for running. This cycle is part of the entire powerup procedure and cannot be directly selected.

Precision	Ability of the instrument to reproduce similar results when a sample is run repeatedly. Precision of the instrument is a %CV, or an SD for diff parameters, based on at least 31 replicate determinations of the same sample. Precision shows the closeness of test results when repeated analyses of the same material are performed. A measure of reproducibility.
Predilute	The process of preparing a minimal amount of blood specimen for analysis by dispensing diluent to an empty tube then adding the blood specimen.A prediluted sample is different than a whole-blood sample. *See* whole blood.
Predilute Cycle	Executes “request sample analysis” using the prediluted specimen.
Primary Mode	Closed Vial mode.
Prime Sweepflow Cycle	Primes the fluidics path from the diluent reservoir through the sweepflow coil and the path between the RBC aperture and the vacuum isolator chamber.
Prime Timeout Cycle	Prepares the Diluter to run samples if Diluter has been idle for 2 hours or more.
Quality Check Cycle	Executes “Request Sample Analysis” using non-labile control as the specimen.
QC (Quality Control)	A comprehensive set of procedures your laboratory sets up to ensure that the instrument is working accurately and precisely.
Reagent Management Card	A program card that manages your reagent usage.
Reproducibility	This procedure checks that the system gives similar results (within established limits) every time it measures the same sample. Also called precision.
Rinse and Mix Cycle	Drains the baths, supplies the rinse, and provides the air for mixing.
Secondary Mode	Open Vial mode.
SD (Standard Deviation)	A measure of variation within a group of samples or a population.
Shift	Consecutive values that abruptly move from one side of the mean to the other then maintain a constant level.
Shutdown Cycle	Cleans the fluidic lines and apertures to help prevent residue buildup, and turns off Hgb lamp.
Software Card	A program card that contains instructions to run the instrument.
Standard Deviation (SD)	A measure of variation within a group of samples or a population.
Startup Cycle	Ensures that the instrument is ready to run; includes turning on Hgb lamp and performing background test.
Stop Bit	A computer code that indicates the end of a character.
Sweep Flow	A steady stream of diluent that flows behind the RBC aperture during sensing periods to keep RBCs from swirling back into the sensing zone.
TABLE OF EXPECTED RESULTS	Assigned values for a control material used for quality control parameters. Usually reported on a package insert shipped with the control material; can be a separate assay sheet.
Trend	Values that continue to increase or decrease gradually over a period of time.
Verification	Procedure to analyze cell controls or whole blood with known values to determine if your control results are within expected range.
Verify Predilute	Procedure that performs the aspirate-verify cycle followed by the dispense-verify cycle.
Voting	In COULTER hematology instruments, the system compares the three counts for RBC, WBC, Plt. Unless at least two counts agree, the system does not accept the count. It displays a code (-----) to indicate a voteout.
Wet Prime Cycle	Primes the fluidics path of the Diluter and baths with diluent and removes small amounts of air that may have leaked into the diluent lines.

Whole Blood	Non-diluted blood; blood and anticoagulant only.
Whole Blood Cycle	Executes “Request Sample Analysis” using whole blood as a specimen.
Zap Aperture Cycle	Clears the aperture using the zap current circuit.

ABBREVIATIONS

Abbreviation	Explanation
µL	microliter
µm	micrometer
A	ampere
AIM	aperture integrity monitor
ANSI	American National Standards Institute
ASCII	American Standard Code for Information Interchange
ASTM	American Society for Testing and Materials
AWG	American Wire Gauge
bps	bits per second
CBC	complete blood count
CDC	Centers for Disease Control and Prevention
CEE	Commission for Electrical Equipment
CHD	Coulter Histogram Differential
cm	centimeter
CSA	Canadian Standards Association
CV	coefficient of variation
diff	differential
dL	deciliter
EDTA	ethylenediaminetetraacetic acid
FDA	Food and Drug Administration
fL	femtoliter
ft	foot or feet
g	gram
gal	gallon
GR	granulocyte
Hct	hematocrit
Hgb	hemoglobin
Hz	hertz
IEC	International Electrical Commission
IQAP	Interlaboratory Quality Assurance Program
L	liter
LY	lymphocyte
m	meter
MCH	mean corpuscular hemoglobin
MCHC	mean corpuscular hemoglobin concentration
MCV	mean corpuscular volume

Abbreviation	Explanation
mL	milliliter
mm	millimeter
MO	monocyte
MPV	mean platelet volume
MSDS	material safety data sheets
mW	milliwatt
n	number
NCCLS	National Committee for Clinical Laboratory Standards
NEMA	National Electrical Manufacturers Association
nm	nanometer
pg	picogram
Plt	platelet
psi	pounds per square inch
QA	quality assurance
RBC	red blood cell
RDW	red cell distribution width
SD	standard deviation
UL	Underwriters Laboratory
Vac	volts of alternating current
Vdc	volts of direct current
VIC	vacuum isolator chamber
VRM	Volts Root Mean Square
WBC	white blood cell

Symbols

Numerics

A

B

C

D

E

F

G

H

I

L

M

N

O

P

Q

R

S

T

U

V

W

Z

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COULTER A^{C}•T diff 2 Analyzer Documentation

■ Reference PN 4237515 (*Black binding)	Use and Function • Installation • Operation Principles • Specifications/Characteristics • Precautions/Hazards • Host Transmission Specifications • Log Sheets • References • Glossary • Abbreviations • Index
■ Operator's Guide PN 4237495 (*Red binding)	Routine Procedures • Cell Controls • Running Samples • Reviewing Results • Calibration • Service and Maintenance • References • Glossary • Abbreviations • Index
■ Operating Summary PN 4237516	Overview of daily procedures and screen icons.
■ Installation and Training Guide diff A^{C}•T Tainer Reagent diff A^{C}•T Pak Reagent PN 4237517	Installing the A^{C}•T diff 2 Analyzer • Learning About the A^{C}•T diff 2 Analyzer • Questions and Answers • Component Locations • Installation and Training Checklists

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